

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NESTED BEAN, INC.,

Plaintiff,

v.

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION; PETER A. FELDMAN in his official capacity as Acting Chair of the Consumer Product Safety Commission; RICHARD L. TRUMKA, JR., in his official capacity as Commissioner of the Consumer Product Safety Commission; ALEXANDER HOEHN-SARIC in his official capacity as Commissioner of the Consumer Product Safety Commission; DOUGLAS DZIAK in his official capacity as Commissioner of the Consumer Product Safety Commission; MARY T. BOYLE in her official capacity as Commissioner of the Consumer Product Safety Commission; DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR. in his official capacity as Secretary of Health and Human Services; CENTERS FOR DISEASE CONTROL AND PREVENTION; SUSAN MONAREZJIM O'NEIL in herthis official capacity as Acting Director of the Centers for Disease Control and Prevention; NATIONAL INSTITUTES OF HEALTH; and JAY BHATTACHARYA in his official capacity as Director of the National Institutes of Health,

Defendants.

CIVIL ACTION NO. 1:25-cv-00389-RGA

**PURSUANT TO RULE 15(a)(1)
FIRST AMENDED COMPLAINT FOR
DECLARATORY RELIEF
(Verified Complaint)**

FIRST AMENDED COMPLAINT FOR DECLARATORY RELIEF

INTRODUCTION

1. This challenge is brought to stop the unlawful and unfounded public statements against “weighted” infant sleep products made by Defendants Consumer Product Safety Commission (“CPSC” or “Commission”), CPSC Commissioner Richard Trumka, Jr., the

Department of Health and Human Services (“HHS”), the Centers for Disease Control and Prevention (“CDC”), and the National Institutes of Health (“NIH”). Defendants have issued inaccurate, misleading, and unlawful public advisories, maligning “weighted” infant sleep products as deadly and hazardous,—including the products developed, designed, produced, and sold by Nested Bean, Inc. (“Plaintiff” or “Nested Bean”)—and advocating that parents and caregivers refrain from using such products. These unlawful actions have severely damaged Nested Bean’s relationships with retailers and investors, destroyed its reputation, and decimated the company.

2. The CPSC is the only federal agency charged with protecting consumers from unreasonable risks of injury from consumer products. The authorizing law provides a regulatory framework for the CPSC to: conduct product safety research, investigations, and testing; assist with the development of voluntary product safety standards; promulgate mandatory consumer product safety standards; collect, maintain, and analyze incident data; file suit to seize imminently hazardous products; and, either through notice-and-comment rulemaking or adjudication, ban “hazardous” products, i.e., products that pose an “unreasonable risk” of harm to consumers. All consumer product safety determinations made by the CPSC must follow the rigorous science and data-driven process set forth by federal law.

3. WeightedNested Bean’s innovative infant sleep products have been around for nearly 15fifteen years. In 2011, Nested Bean was Ms. Gangan founded by a Nested Bean after experiencing the challenge of being the working mother struggling withof a baby who would not go to sleep, and stay asleep, without being held, unless she placed her hand gently on her baby’s chest. This is a relatable challenge faced by millions of parents, who must juggle the demands of caring for a newborn sleepless nights, who happened towithout the benefit of sufficient parental

leave or help. Because of these challenges, many of these parents revert to unsafe practices, such as placing loose objects on or near their baby, co-sleeping in the parent's bed, using sleep positioners, or other unsafe infant sleep products such as nests or inclined sleep products. While these practices are not recommended by the CPSC, the fact is that they persist in American homes, a reality which researchers have an engineering background and over a decade of developing consumer facing products documented to be true and which can be seen anecdotally among parents in support groups, online in blogs, and in other guidance to new parents.

Determined to help discourage this behavior and to provide relief for other parents, Nested Bean rigorously researched, designed, and developed its Ms. Gangan—an engineer by profession with a career of spanning over fifteen years in consumer facing web products before founding Nested Bean—set out to create a product for child that would effectively and safely provide the baby with the proven benefits of the sense of being comforted through touch, in a manner that is consistent with safe sleep guidance, such that it would place babies on their back, in the crib, and more importantly without any loosely placed aids.

4. Nested Bean's innovative products apply a lightly padded area on the upper torso of its wearable products where caregivers usually place their reassuring palm, to extend the principles of parental simulated touch intervention, which is proven safe and effective in Neonatal Intensive Care Units ("NICU") on the most vulnerable of low-birth-weight babies. In an attempt to serve a greater public health benefit in the most responsible manner, Nested Bean's cautious designs have maintained safety before bringing it to market at the forefront. In designing the inaugural product, Nested Bean reviewed ten years of public incident data for surrounding conditions, consulted Human Factors design experts, and sent prototypes for lab tests, making improvements at each iteration. Nested Bean's design intentionally sought to avoid

application of the padded portions containing filling on areas that could potentially hinder mobility or cause overheating, both being common contributors in historical safety incidents.
Today, Nested Bean's product line includes swaddles, sleep sacks, and pajamas, all with a sewn-in, lightly padded center on the upper torso of each product. Each product comes in a variety of sizes appropriate for different ages, sizes, and developmental stages of the baby. Consistent with the company's ethos for honesty and transparency, Nested Bean coined the phrase and marketed its products as "weighted" infant sleep products.

5. Nested Bean is deeply committed to infant safety. It continues to invest and undergo safety voluntary testing and scientific research, even though it is under no obligation to do so. Nested Bean's safety record speaks for itself. It has sold over 2.5 million products without a single known incident or CPSC investigation report concluding that any of its products are hazardous. In fact, the CPSC staff evaluated three of its products—considering in detail each product's design and construction—to test whether any of the products could rise over the baby's nose or mouth and present a risk of suffocation. This thorough evaluation concluded with a satisfactory closing report and a determination that no further action was necessary.

3.—Due to the increase in global competitors over the years selling knock-off products, Nested Bean has actively participated ~~and~~, cooperated ~~with the CPSC~~, and urged the Advancing Standards Transforming Markets International ("ASTM"), subcommittee F15.19 on infant bedding, to: first create a category and definition for infant sleep products, such as swaddles, sleep sacks, and pajamas, that contain added filling resulting in additional weight beyond just the base fabric; and second to create voluntary safety standards for this newly created category of "weighted" or "filled" infant sleep products to (a) provide guidance for manufacturers, in the form of weight thresholds for added filling, and (b) protect consumers from unscrupulous manufacturers. copy-cat foreign manufacturers entering the U.S. on online marketplaces. Nested Bean's safety record speaks for itself. It has sold over 2.5 million

~~products and has not had a single known incident or CPSC investigation report concluding that any of its products are hazardous.~~

6. To date, the ASTM has not adopted a definition or voluntary standard for “weighted” infant sleep products.

4.7. Additionally, to date, the CPSC has not: adopted any voluntary or a definition of “weighted” infant sleep products; adopted any mandatory product safety standards for weighted infant sleep products; adopted a definition of weighted “weighted” infant sleep products; identified a hazard pattern with Nested Bean’s products or “weighted” infant sleep products; nor issued a recall, stop sale, or ban for Nested Bean’s products.

5.8. Despite the fact that the Even though CPSC has not defined or created a category of “weighted” infant sleep products nor made any determinations, such as a recall, stop sale, or ban, regarding “weighted” infant sleep products, sometime in 2022–2023, the HHS, and its subagencies CDC and NIH, amended their Safe to Sleep®¹ guidance for the public to advocate against the use of “weighted” infant sleep products. Then the CPSC, rather than following their own statutory requirements for making consumer product safety determinations, simply followed and echoed the unlawful HHS guidance. By 2022, Nested Bean had completed eleven years in business with over 2 million products sold and had maintained a stellar safety record.

6.9. Compounding the Adding to these unlawful actions, one (now-former) Commissioner made it his personal mission to destroy the industry of “weighted” infant sleep

¹ The Safe to Sleep® campaign “is led by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), part of the National Institutes of Health, and benefits from a dedicated group of Collaborators.” <https://safetosleep.nichd.nih.gov/campaign> (last visited Oct. 17, 2025). Included in the list of Collaborators is the American Academy of Pediatrics (“AAP”), the CDC, and the CPSC. <https://safetosleep.nichd.nih.gov/campaign/partners> (last visited Oct. 17, 2025).

products. Even though the CPSCCommission: (1) had not (and has not) defined or created a category of “weighted” infant sleep products; (2) had not (and has not) identified a hazard pattern associated with “weighted” infant sleep products; and the CPSC(3) publicly admitted that it did not have enoughlacked sufficient data necessary to begin the rule makingrulemaking process for a mandatory product safety standard, then-Commissioner Trumka wrote letters to major retailers and announced publicly that “weighted” infant sleep products were dangerous and presented an unreasonable risk to consumers.

7.10. BecauseAs a direct result of Trumka’s actions, major retailers dropped Nested Bean’s products almost immediately after receiving Trumka’s letter, thereby decimating Nested Bean’s business.

8.11. Defendants will continue these unlawful actions unless and until a Court upholds the rule of law. Therefore, this Court should grant Plaintiff’sPlaintiff’s requested relief.

PARTIES

9.12. Plaintiff Nested Bean, Inc. (“Nested Bean”) is a corporation incorporated in Delaware, primarily engaged in the business of designing, manufacturing, and selling infant and toddler products, including weighted infant sleepwear: marketed as “weighted”.

10.13. Defendant Consumer Product Safety Commission (“CPSC” or “Commission”) is the federal agency given limited authority to regulate consumer products. Its headquarters are in Bethesda, Maryland.

11.14. Defendant Peter A. Feldman is sued in his official capacity as Acting Chair of the Consumer Product Safety Commission. He was nominated by President Trump and began serving a seven-year term on October 5, 2018.

12.15. Defendant Commissioner Richard L. Trumka, Jr. is sued in his official capacity as

former Commissioner of the Consumer Product Safety Commission. He was nominated by President Biden and began serving a seven-year term on October 27, 2021. On or about May 8, 2025, President Trump removed Mr. Trumka from office. Mr. Trumka has challenged his removal in court, and his case is currently stayed in the United States Court of Appeals for the Fourth Circuit pending a decision by the U.S. Supreme Court in *Trump v. Slaughter*, No. 25-332.²

13.16. Defendant Alexander Hoehn-Saric is sued in his official capacity as former Commissioner of the Consumer Product Safety Commission. He was nominated by President Biden and began serving a seven-year term on July 13, 2021. On or about May 8, 2025, President Trump removed Mr. Hoehn-Saric from office. Mr. Hoehn-Saric has challenged his removal in court, and his case is currently stayed in the United States Court of Appeals for the Fourth Circuit pending a decision by the U.S. Supreme Court in *Trump v. Slaughter*, No. 25-332.

Id.

14.17. Defendant Douglas Dziak is sued in his official capacity as Commissioner of the former Consumer Product Safety Commission. He was nominated by President Biden and began serving on March 25, 2024, to complete a seven-year term that would have expired on October 27, 2024. On August 22, 2025, Commissioner Dziak announced his resignation, effective immediately.³

15.18. Defendant Mary T. Boyle is sued in her official capacity as former Commissioner

² See *Boyle v. Trump*, Case No. 8:25-cv-01628 (D. Md. Oct. 8, 2025) (Order from the Fourth Circuit placing the case in abeyance until a decision by the U.S. Supreme Court in *Trump v. Slaughter*, No. 25-332).

³ Douglas Dziak, *Statement of Commissioner Douglas Dziak: Goodbye, Farewell, and Amen*, United States Consumer Product Safety Commission (Aug. 22, 2025), <https://tinyurl.com/54jr4sfu>.

of the Consumer Product Safety Commission. She was nominated by President Biden and began serving a seven-year term on June 22, 2022. On or about May 8, 2025, President Trump removed Ms. Boyle from office. Ms. Boyle has challenged her removal in court, and her case is currently stayed in the United States Court of Appeals for the Fourth Circuit pending a decision by the U.S. Supreme Court in *Trump v. Slaughter*, No. 25-332. Id.

16.19. Defendant Department of Health and Human Services (“HHS”) is a Cabinet-level agency within the Government of the United States. It is headquartered in Washington, District of Columbia D.C.

17.20. Defendant Robert F. Kennedy, Jr. is sued in his official capacity as Secretary of Health and Human Services.

18.21. Defendant Centers for Disease Control and Prevention (“CDC”) is an operating division of HHS and an agency under 5 U.S.C. § 551(1). It is headquartered in Atlanta, Georgia, and maintains offices in Washington, District of Columbia D.C.

19.22. Defendant Susan MonarezJim O’Neil is sued in herhis official capacity as Acting Director of the Centers for Disease Control and Prevention.

20.23. Defendant National Institutes of Health (“NIH”) is an operating division of HHS and an agency under 5 U.S.C. § 551(1). It is headquartered in Bethesda, Maryland.

21.24. Defendant Jay Bhattacharya is sued in his official capacity as Director of the National Institutes of Health.

JURISDICTION AND VENUE

22.25. Plaintiff seeks declaratory relief (28 U.S.C. §§ 2201, 2202; 5 U.S.C. § 706) and attorneys’ fees (28 U.S.C. § 2412, 42 U.S.C. § 1988) against the Commission for its actions in adopting and failing to rescind the Safe to Sleep Guidelines® guidelines that recommend against

“weighted” infant sleep products, and its actions in publishing and failing to retract inaccurate and misleading statements by Trumka because such actions violate Section 6(b) of the Consumer Product Safety Act (“CPSA” or “Act”) (15 U.S.C. § 2055(b), 16 C.F.R. § 1101.1—1101.52); ~~is are~~ not authorized by the CPSA (5 U.S.C. § 706(2)(A)); ~~exceeds exceed~~ statutory authority (5 U.S.C. § 706(2)(C)); ~~failed to follow were taken without following proper~~ procedure (5 U.S.C. § 706(2)(D)); ~~is and are~~ arbitrary and capricious (5 U.S.C. § 706(2)(A)); ~~and thereby entitles Plaintiff to~~ ~~attorneys’ fees (28 U.S.C. § 2412, 42 U.S.C. § 1988 — attorneys’ fees).~~

23.26. Plaintiff also seeks declaratory relief (28 U.S.C. §§ 2201, 2202) ~~and attorneys’ fees (28 U.S.C. § 2412, 42 U.S.C. § 1988)~~ against ~~Commissioner~~ Trumka for his letters to major retailers and his public social media statements recommending against Nested Bean products and ~~the class of~~ “weighted” infant sleep products because ~~it is his actions are~~ *ultra vires* (5 U.S.C. § 702); ~~violates they~~ ~~violate Section 6(b) of the CPSA (15 U.S.C. § 2055(b), 16 C.F.R. § 1101.1—1101.52); and violate Plaintiff’s~~ Fifth Amendment right to due process (42 U.S.C. § 1983—~~constitutional rights); and thereby entitles Plaintiff to attorneys’ fees (28 U.S.C. § 2412, 42 U.S.C. § 1988 — attorneys’ fees).~~

24.27. Plaintiff also seeks declaratory relief (28 U.S.C. §§ 2201, 2202; 5 U.S.C. § 706) against Defendants HHS, Robert F. Kennedy, Jr., CDC, ~~Susan Monarez Jim O’Neil~~, NIH, and Jay Bhattacharya for their actions in adopting the Safe to Sleep Guidelines® guidelines that recommend against “weighted” infant sleep products because none of those agencies have the authority to make consumer product safety determinations and, as such, the actions are *ultra vires* (5 U.S.C. § 702); ~~exceed statutory authority (5 U.S.C. § 706(2)(C)); and are arbitrary and capricious (5 U.S.C. § 706(2)(A)).~~

25.28. Plaintiff is also seeking to hold unlawful and set aside the Safe to Sleep

Guidelines® guidelines that recommend against “weighted” infant sleep products (5 U.S.C. § 706).

26.29. The federal government has waived sovereign immunity to this action under 5 U.S.C. § 702.

27.30. This Court has jurisdiction over these federal claims (28 U.S.C. § 1331), review of agency action (5 U.S.C. § 702), and redress for deprivation of civil rights (28 U.S.C. § 1343(a)(3)) against these federal Defendants (28 U.S.C. §§ 1346).

28.31. Plaintiff Nested Bean has exhausted administrative remedies; the Commission’s response to plaintiff’s Plaintiff’s letter demanding retraction on December 20, 2024, is a final agency action that is judicially reviewable under the Administrative Procedure Act (“APA”). 5 U.S.C. §§ 704, 706.

29.32. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because (1) Defendants are United States agencies or officers sued in their official capacities, (2) Plaintiff’s Plaintiff’s place of incorporation is Delaware, (3) no real property is involved, and (4) a substantial part of the events or omissions giving rise to the Complaint occurs within this judicial district.

LEGAL BACKGROUND

The Consumer Product Safety Commission

30.33. The Consumer Product Safety Act (“CPSA”), 15 U.S.C. § 2051 et seq., enacted in 1972, established the Consumer Product Safety Commission (“CPSC” or “Commission”) and gives the Commission authority to develop product safety standards, to ban products under certain circumstances, and to pursue recalls of products that present a substantial product hazard. 15 U.S.C. §§ 2056, 2057, 2058.

31.34. The CPSA was enacted to address concerns that “consumer products which present unreasonable risks of injury” were available to consumers and that the existing regulatory framework was either inadequate or burdensome to manufacturers. 15 U.S.C. § 2051(a)(1), (4), and (5).

32.35. The Commission’s purpose is: “(1) to protect the public against unreasonable risks of injury associated with consumer products; (2) to assist consumers in evaluating the comparative safety of consumer products; (3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and (4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.” 15 U.S.C. § 2051(b).

33.36. To fulfill its purpose, the CPSA authorizes the Commission to: collect, maintain, and analyze incident data; assist in development of voluntary product safety standards; conduct product safety research, investigations, and product tests; promulgate consumer product safety standards establishing performance or warning requirements; address imminently hazardous products; and ban hazardous products. *See* 15 U.S.C. §§ 2054, 2056, 2058, 2061, and 2064.

34.37. In promulgating consumer product safety standards, the Commission must follow the procedures set forth by both the CPSA and the Administrative Procedure Act (“APA”).APA.

35.38. A product safety standard requirement “shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product.” 15 U.S.C. § 2056(a).

36.—“A consumer product safety rule shall express in the rule itself the risk of injury which the standard is designed to eliminate or reduce.” 15 U.S.C. § 2058(e).

37.39. “In promulgating such a rule the CommissionerCommission shall consider relevant available product data including the results of research, development, testing, and

investigation activities conducted generally and pursuant to this Act.”⁵ ^{....} 15 U.S.C. § 2058(e).

38.40. “Prior to promulgating a consumer product safety rule, the Commission shall consider, and shall make appropriate findings for inclusion in such rule with respect to—(A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce; (B) the approximate number of consumer products, or types or classes thereof, subject to such rule; (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety.” 15 U.S.C. § 2058(f)(1).

39.41. “The Commission shall not promulgate a consumer product safety rule unless it has prepared, on the basis of the finding of the Commission under paragraph (1) and on other information before the Commission^{....} 15 U.S.C. § 2058(f)(2). Also, on the basis of those findings, the final regulatory analysis must describe the potential benefits, costs, and alternatives.

40.42. The CPSA also permits the Commission to ban hazardous products which present “an unreasonable risk of injury”²² but such action requires the same evidence and data-backed determination. 15 U.S.C. § 2057.

41.43. CPSC may not promulgate a rule banning a product unless it finds “that no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with such product.” 15 U.S.C. § 2058(f)(3)(c).

44. According to the CPSA, Commissioners may be removed by the President only for “neglect of duty or malfeasance in office but for no other cause.” 15 U.S.C. § 2053(a).

CPSC Public Disclosure Process

42.45. The CPSA also dictates how the Commission, the individual commissioners, and CPSC staff may publicly discuss consumer products. *See* 15 U.S.C. § 2055.

43.46. No less than ~~15~~fifteen days prior to public disclosure of information, ~~where from which~~ the identity of ~~the~~ manufacturer is readily ascertainable, the Commission must notify the manufacturer about the information to be disclosed and must provide the manufacturer the opportunity to comment on such information. 15 U.S.C. § 2055(b)(1).

44.47. A manufacturer is “readily ascertainable,” requiring notice before disclosure, “when a reasonable person receiving the information in the form in which it is to be disclosed and lacking specialized expertise can readily ascertain from the information itself the identity of the manufacturer or private labeler of a particular product.” 16 C.F.R. § 1101.13.

45.48. Then, before ~~it~~the Commission itself or any Commissioner publicly discloses information “from which the identity of such manufacturer ~~....~~ may be readily ascertained,” the Commission must “take reasonable steps to assure” that the disclosure is (1) accurate, (2) fair in the circumstances, and (3) reasonably related to effectuating the purposes of the Consumer Product Safety Act. *Id.* 15 U.S.C. § 2055(b)(1). In other words, if the CPSC, ~~or~~ an individual Commissioner, or any CPSC staff member is going to disclose to the public information that would enable an average person to easily identify ~~the~~ manufacturer, then the CPSC must provide that manufacturer with notice and opportunity to comment on the proposed disclosure.

~~The~~Then ~~The~~ CPSC must then include in the disclosure any comments or other information provided by the manufacturer in response to the information. ~~15 U.S.C. § 2055(b)(1)~~ *Id.*

46.49. ~~If Furthermore, whenever~~ the CPSC ~~is going to disclose to the public~~publicly discloses information that reflects on the safety of a specific consumer product or a class of

consumer products, ~~then the CPSC still has an obligation to make sure it must ensure~~ that the information being disclosed is accurate and not ~~inaccurate or~~ misleading—regardless of whether the identity of ~~the~~any manufacturer is easily identifiable. 15 U.S.C. § 2055(b)(6).

47.50. The disclosure responsibilities under the CPSA apply to both the Commission and individual Commissioners. The Act's public-disclosure procedure “shall apply whenever information is to be disclosed by the Commission, *any member of the Commission*, or any employee, agent, or representative of the Commission in an official capacity.” 15 U.S.C. § 2055(d)(2) (emphasis added).

48.51. Likewise, The Act allows consumer-product manufacturers to seek a retraction ~~ean~~ be requested for of inaccurate or misleading statements made by individual commissioners.

“Any manufacturer, distributor or retailer of a consumer product or any other person may request a retraction if he/she believes the Commission or *an individual member*, employee, agent, contractor or representative of the Commission has made public disclosure of inaccurate or misleading information, which reflects adversely either on the safety of a product with which the firm deals or on the practices of the firm.” 16 C.F.R. § 1101.52(b) (emphasis added)...

16 C.F.R. § 1101.52(b) (emphasis added).

52. Then “[,

[i]f the Commission finds that, in the administration of the Act, it has made public disclosure of inaccurate or misleading information which reflects adversely upon the safety of any consumer product or class of consumer products, or the practices of any manufacturer, private labeler, distributor, or retailer of consumer products, it shall, in a manner equivalent to that in which such disclosure was made, take reasonable steps to publish a retraction of such inaccurate or misleading information.” ~~15 U.S.C. § 2055(b)(7).~~

15 U.S.C. § 2055(b)(7).

CPSC Clearance Procedures

53. The CPSA requires that “the Commission shall establish procedures designed to ensure that [information disclosed by the Commission] is accurate and not misleading.” 15

U.S.C. § 2055(b)(6). As such, the Commission created “Clearance Procedures For Providing Information To The Public Directives,” (“Clearance Procedures”) to ensure that information disclosed to the public about consumer products are accurate, not misleading, and in accordance with the CPSA. See CPSC Directive 1450.2.⁴ Under the Clearance Procedures, “Clearance” means “a careful review and written approval of the information to be disclosed by each Assistant or Associate Executive Director (AED) (or delegate) whose area of responsibility is involved in the disclosure in order to eliminate inaccurate or misleading statements.” *Id.* at (7)(a). And “[n]o information shall be disclosed until approved as set out in this directive.” *Id.* These clearance procedures “apply to any release of information initiated by the Commission, including information disseminated on the agency’s website, regardless of whether the information disclosed would enable the public to ascertain readily the identity of a manufacturer or private labeler[,]” whether the disclosure is written or oral, and it applies “Commission-wide, to all employees, agents, and representatives” whenever publicly disclosing information “that reflects on the safety of consumer products.” *Id.* at (1)(a), (2).

54. The Clearance Procedures for public disclosure requires five clearances: technical, program, policy, editorial, and legal. See *id.* at (7)(a) and (b).

55. Technical and Scientific Clearance requires that the information to be disclosed to the public must be supported by:

- (a) data in Commission files or in currently applicable literature;
- (b) articulated technical judgment that is both reduced to writing and based on consideration of all relevant factors; or
- (c) a report prepared by a contractor to the Commission and such report has been subject to a review process by Commission staff.

Id. at (7)(a)(1)(a)–(c).

⁴ <https://www.cpsc.gov/About-CPSC/Policies-Statements-and-Directives/Clearance-Procedures-For-Providing-Information-To-The-Public-Directives> (Jan. 14, 2003).

56. Program Clearance “means that the statement accurately reflects the status of programs and projects, enforcement activities, litigation, and planning, where appropriate.” *Id.* Commissioners may only be removed by the President for “neglect of duty or malfeasance in office but for no other cause.” at (7)(a)(2).

57. Editorial Clearance “means that the statement retains style and coherence without changing technical, program, or legal meanings” *Id.* at (7)(a)(3).

58. Legal Clearance “means that the statement is consistent with applicable laws and regulations, that any possibly inaccurate or misleading statements are eliminated and that any statements of Commission policy are accurate.” *Id.* at (7)(a)(5).

59. The Clearance Procedures also requires the use of disclaimers “in all outside publications in which an employee uses his or her official title or states an affiliation with the Commission. The disclaimer shall read as follows: ‘The opinion expressed by(), an employee of the Consumer Product Safety Commission, does not necessarily represent the views of the Commission.’” *Id.* at (7)(f)(2)(b).

49.1. 15 U.S.C. § 2053(a).

Advancing Standards Transforming Markets

50.60. Advancing Standards Transforming Markets International (“ASTM”), The ASTM, formerly known as American Society for Testing and Materials, is an organization that develops technical standards for a wide range of materials, products, systems, and services.

51.61. Since the 1970’s CPSC has collaborated with ASTM to create standards for emerging hazards. ASTM is a private, voluntary consensus standards development organization which creates and maintains product standards using a rigorous approach to assure that standards are developed in an open, fair, and balanced system with input from all stakeholders. ASTM

Committee F15 on Consumer Products was established in 1973 at the request of CPSC.⁵ and, since then, CPSC has collaborated with ASTM to create voluntary standards for emerging hazards.⁶ In, or around, 2021, ASTM Committee F15 created a subcommittee, F15.19 on Infant Bedding.

52.62. “CPSC has about 500 employees and is responsible for overseeing safety issues relative to thousands of product categories. ASTM technical committees provide stakeholder expertise that could not otherwise be found among CPSC staff.”⁷ “

The development of a new or revised ASTM International standard is often initiated when CPSC approaches ASTM regarding the need for a particular safety standard. CPSC staff will provide a list of people who might be interested in developing the standard. If the stakeholders agree, ASTM will then establish a committee or subcommittee and solicit people and organizations to become involved. When a committee is organized, ASTM staff explains the ASTM system and how it works to the participants. Assuming the participants decide to move ahead, they will then work on different aspects of the subject such as safety performance provisions, and labeling and testing protocols. When the CPSC feels it appropriate, the ASTM standard will be incorporated by reference and any additional safety provisions are then added to the CPSC mandatory rule.” *Id.*

The

Id.

53.63. To date, the ASTM Subcommittee F15.19 on Infant Bedding,⁸ which purportedly includes “weighted” infant sleep products, has not reached a consensus on a definition or

⁵ Committee F15 on Consumer Products, <https://www.astm.org/membership-participation/technical-committees/committee-f15>.

⁶ Committee F15 on Consumer Products, <https://www.astm.org/membership-participation/technical-committees/committee-f15> (last visited Oct. 17, 2025).

⁷ Alan Earls, *The CPSC and ASTM Collaboration*, Standardization News, January/February 2011, (July 26, 2019) <https://sn.astm.org/features/cpsc-and-astm-collaboration-jf11.html>.

⁸ Subcommittee F15.19 on Infant Bedding, <https://www.astm.org/membership-participation/technical-committees/committee-f15/subcommittee-f15/jurisdiction-f1519>. Subcommittee F15.19 on Infant Bedding, <https://www.astm.org/membership-participation/technical-committees/committee-f15/subcommittee-f15/jurisdiction-f1519>.

voluntary product standards for ~~this category of these~~ consumer products.⁹

The Public Health Service Act

54.64. The Public Health Service Act (“PHSA”) authorizes the Secretary of HHS to “develop, support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood[.]” 42 U.S.C. § 300c-11(a). Such programs and activities include~~:, among other things:~~ (a) supporting CDC registries collecting certain data; and (b) awarding grants or cooperative agreements to States, Indian Tribes, and Tribal organizations to, among other things, improve data collection, develop best practices, and educate health care professionals and the public about risk factors. 42 U.S.C. § 300c-11(a)(2). ~~The purpose of these programs is data collection.~~

55.65. The Secretary of HHS must make sure that there are adequate funds applied to leads and findings from research “in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.” 42 U.S.C. § 300c-12.

~~56.—The Secretary of HHS must continue activities related to still birth, sudden unexpected infant death, and sudden unexplained death in childhood, such as collecting data, educating the public, and collaborating with federal and state agencies. 42 U.S.C. § 300e-13.~~

57.66. ~~Then the~~The Secretary of HHS must make regular reports to Congress describing all the activities being carried out by the HHS, CDC, and NIH, data collection, and assessment of various approaches related to stillbirth, sudden unexpected infant death, and sudden unexplained

⁹ Proposed voluntary standards failed to pass resolution, <https://www.astm.org/membership-participation/technical-committees/workitems/workitem-wk81176>. <https://www.astm.org/membership-participation/technical-committees/workitems/workitem-wk81176>.

death in childhood. 42 U.S.C. §§ 300c-13(b), 300c-14.

67. The Sudden Infant Death Syndrome (“SIDS”) Act of 1974 (Public Law 93-270) directed the National Institute of Child Health and Human Development (“NICHD”), a subset of NIH, to lead federal research efforts to identify the causes of SIDS, develop preventive strategies, and provide information to educate the public about SIDS.

68. In 1994, the Safe to Sleep® campaign began, led by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, part of NIH.¹⁰ The Safe to Sleep® campaign was originally called the Back to Sleep campaign, “named for its main recommendation for all healthy babies to be placed on their backs to sleep to reduce the risk of Sudden Infant Death Syndrome (SIDS).” *Id.* Since then the campaign has expanded “to address not only SIDS, but also other sleep-related infant deaths.” *Id.*

69. For the Safe to Sleep® campaign, NICHD collaborates with other federal agencies, such as the CDC and CPSC, and other organizations including the AAP.¹¹

FACTUAL ALLEGATIONS

Plaintiff - Nested Bean

58.70. Plaintiff Nested Bean, Inc. (“Nested Bean”) develops, designs, manufactures, and sells infant and toddler products, including infant swaddles, sleeping bagssacks, and pajamas that are lightly “weighted” to mimic the gentle touch of a parent.

59.71. Nested Bean is a small immigrant, minority woman-owned business founded in 2011. Nested Bean grew out of its founder, Manasi Gangan’s, struggle to find a solution to help her own child sleep restfully and independently as a working mother of a baby who would not go

¹⁰ See <https://safetosleep.nichd.nih.gov/campaign/history>.

¹¹ <https://safetosleep.nichd.nih.gov/campaign/partners>.

to sleep unless ~~a-parents~~she placed ~~their~~her hand gently on the child's center. As soon as ~~the~~parent's~~her~~ hand was removed, her child would wake immediately.

60.72. Ms. Gangan, a 15-year veteran in the technology industry, set out to create a product that would effectively and safely provide the baby with the proven benefits of the sense of being comforted through touch, in a manner that is consistent with safe sleep guidance, such that it would place babies on their back, in the crib, without any loosely placed aids. Nested Bean's products are designed to foster safe sleep practices by allowing parents,~~—~~who may otherwise resort to unsafe practices such as co-sleeping with their baby, or using ~~loungers or~~ inclined products,~~—~~for sleep~~—~~ to ~~instead~~ place ~~them~~infants in a safe crib environment with no soft bedding or other objects.

61.73. Ms. Gangan was inspired by neonatal units in hospitals that were utilizing positional aids with polypropylene filling to simulate the familiar pressure experienced in the womb or from parental touch, mimicking the touch or cradling of a caregiver's hand. Encouraged by ~~a~~ neonatal research study results on the soothing effects of parental simulated touch, Ms. Gangan embarked on a mission to create a solution that would provide restful sleep for both little ones and their parents. Ms. Gangan began her efforts to develop a line of sleepwear that is designed to mimic the gentle touch of a parent who instinctively places her hand on her baby's chest to help soothe ~~babies~~a baby back to sleep.

62.74. Ms. Gangan's experience in product development and risk assessment guided her cautious approach to the design and development of the new innovative sleepwear. In designing Nested Bean's products, Ms. Gangan followed guidance of the International Organization for Standardization ("ISO") for consumer product safety (ISO 10377¹²~~—guidance~~)—i.e., that safety is

¹² ISO 10377:2013(E), available at <https://www.iso.org/standards.html>.

“freedom from unacceptable risk”¹³—and the CPSC recommendations for best practices—i.e., that the product “not only meets or exceeds the requirements of federal safety laws, but also is designed and manufactured as safely as possible.”¹⁴ She sought advice from sleep safety experts and safety labs to ensure that safety was front and center throughout the design, development, and production phases.

63.75. Nested Bean shared early designs and prototypes with accredited safety labs for a design evaluation. Based on the safety lab’s evaluation and recommendations received during the design and development phase, Nested Bean made critical design changes: ~~to prevent rebreathing through the parts containing filling~~. Nested Bean updated the prototype and then shared it with Human Factor Design experts to receive safety evaluation ~~in case of rebreathing through the parts containing filling~~. Nested Bean then adopted the experts’ safety recommendations. Nested Bean also consulted with an accredited safety lab to receive a comprehensive report of mandatory, and a few voluntary, safety test recommendations using international test methods from major global territories such as the United States, Canada, Europe, China, and Japan. Materials chosen throughout the supply chain underwent applicable mandatory testing, as well as additional voluntary testing. Nested Bean then consulted with safety experts to define the warnings to be added to product labels. All of these safety measures in the design, development, and production were done in 2011–2012 before a single product went to market.

76. Nested Bean designed a sleepwear product with sewn-in filling in the form of a lightly weighted pad applied to the infant’s upper torso. This pad weighs between thirty grams to

¹³ ISO 10377:2013(E), Section 2 (Terms and definitions).

¹⁴ CPSC Manufacturing Best Practices, available at <https://www.cpsc.gov/business-manufacturing/business-education/business-guidance/BestPractices>—(last visited Oct. 17, 2025).

ninety grams depending on the baby's size, and its location of application and area of distribution are designed to maintain a certain mass-over-area ratio proportionate to the infant's body weight for ages up to twenty-four months. In fact, the pad's weight for the smallest babies starts at just thirty grams—the equivalent of six quarters, or just about one ounce. One ounce is about 1/112th the weight of the smallest child who can use the product. As babies age to over fifteen months, larger sizes never use more than ninety grams of weight, or three ounces. The mass of this added filling is light enough to mimic a parent's gentle palm and isolated enough on the chest to not hinder the child's mobility or cause overheating. It is comparable in weight and location to the mass of other commonly found products in a baby's environment, such as a car seat chest-clip or a plushie (to hold a pacifier in place) that rests on the baby's chest as the baby sleeps. In fact, some infant sleep products, from other manufacturers, with extra filling for winter months or colder temperatures, though not marketed as "weighted", weigh significantly more than a Nested Bean product that is marketed as "weighted".

64.77. Ms. Gangan's unwavering commitment to safety, innovation, and research underpins Nested Bean's success. This is evidenced by the stellar safety record the company has maintained withafter over 2.5 million products sold. There has been no hazard pattern identified with Nested Bean's products, nor injuries or deaths attributed to them. any injuries or deaths attributed to them. In fact, in 2023 the CPSC conducted a safety review of three of Nested Bean's products to evaluate a potential of suffocation risk, and CPSC staff concluded that the product did not need any further action under section 15 of the Consumer Product Safety Act, 15 U.S.C. § 2064.

65. Nested Bean listens to, supports, and provides valuable insights to parents while advocating best practices for safe sleep. The company has earned widespread acclaim from

~~parents, receiving tens of thousands of positive reviews for its effectiveness in helping their babies sleep, and has actively engaged with the parenting community through social platforms. Nested Bean reviews and analyzes customer comments and anecdotal observations left on its own website, retailers' sites, and the CPSC's publicly searchable consumer database saferproducts.gov to identify possible improvements.~~

66.78. Even with its amazing safety record, Nested Bean remains committed to safety and compliance. Nested Bean frequently reviews CPSC regulations ~~that apply to infant clothing and infant sleepwear. To ensure continued safety, Nested Bean commissioned a preliminary study in 2023 to investigate the potential effects of applying incremental weights to an infant's chest while in a supine position. The results of that study found that the peripheral oxygen saturation and pulse rate for weights between 0g and 30g were in the same statistical grouping.~~ Nested Bean's products are within this range of weight concentration that shows no hazard pattern. ~~for infant clothing and infant sleepwear and other adjacent industries to determine whether there is any possible application to Nested Bean's products' innovative features and whether Nested Bean should voluntarily apply the regulation in an effort to continuously improve the safety of its products.~~

67. Additionally, the CPSC's own review of Nested Bean's products showed no identifiable hazard. In 2023, the Office of Compliance and Field Operations ("Office of Compliance"), the compliance branch of the CPSC, conducted a four month review of Nested Bean's products to assess the risk of suffocation. After reviewing Nested Bean's products, the CPSC staff found no identifiable hazard pattern, so the compliance staff's attorney sent Nested Bean a closing letter stating that no further action was warranted.

68. Nested Bean uses minimal weight in its products, ranging from 30 to 90 grams

~~depending on the baby's size. This aligns with the 30–50 grams of pressure applied by an infant car seat harness and chest clip or winter clothing found commonly in the market and although they are not marketed as “weighted” they can weigh significantly more than a Nested Bean product. Among CPSC’s sample market scan, Nested Bean’s products fall in the 25th–55th percentile for weight and are much lighter than many products containing filling meant to add warmth or weight which are not labeled or marketed as “weighted.”¹⁵~~

79. Nested Bean is committed to creating standards and definitions for the class of wearable infant sleep products, including the category of filled infant sleep products, Nested Bean’s commitment to safety included commissioning a preliminary nonpublished study in 2023, at its own expense, to investigate the potential effects of applying incremental weights to an infant’s chest. Five infants between two and five months of age participated. The study found that the oxygen saturation and pulse rate under a no-load condition (or under 0g) and at a load of 30g, applied over the chest across an area of 10.6 sq. inch, were in the same statistical grouping. The pulse rate and the oxygen saturation recorded at 30 grams were within allowable healthy ranges. Each of Nested Bean’s products applies a weight concentration ratio of 30 grams over 10.6 sq inches. Therefore, while its products may—depending on the infant’s age—include up to 90 grams (3 oz.) of filling, the weight concentration is always maintained at the ratio of 30 grams over 10.6 sq inch by distributing the added filling over a proportionately wider area.

80. While the study was preliminary, Nested Bean shared its findings with the wider juvenile industry to enhance the collective knowledge of all stakeholders and prompt continuous research. Nested Bean believed this effort would benefit several industries, including car seat

¹⁵ CPSC Staff Comments on Wearable Infant Blankets, transmitted November 16, 2023, <https://perma.cc/7H6C-WEE4>.

manufacturers, given that a car seat chest clip is typically within the same weight range and location on the infant's body (without including the weight and pressure of the harness) as the lightly padded area in Nested Bean products.

69.81. Given its stellar safety record and experience of almost fifteen years, Nested Bean is committed to helping the ASTM committee's ongoing effort to create definitions and standards for its products, and similar wearable infant sleep products, in order to raise the bar on infant sleep safety and protect consumers from unscrupulous manufacturers. Because there is no legal definition currently or a consensus definition of "weighted", among stakeholders, numerous manufacturers are selling infant products with heavy filling making them that is significantly heavier than Nested Bean products, although. Some of these heavier products may are not being labeled or marketed as "weighted." Nested Bean has actively contributed to the collaborative process with the ASTM F15.19, the Wearable Infant Blankets Subcommittee, in working towards developing a voluntary safety standard for wearable infant blankets and swaddles. Nested Bean has dedicated significant resources and supported independent research and consumer studies to bring greater insight to demonstrate how innovation can be balanced with safety.

CPSC Weighted Sleep Research and Rejection of Proposal to Pursue a Mandatory

Standard for Weighted Infant Sleep Products

The ASTM F15.19 subcommittee for wearable infant blankets has not CDC, NIH, and AAP Safe to Sleep® Guidance

82. Sometime in 2022–23, the NIH and CDC, through the Safe to Sleep® campaign, revised its policy and adopted any voluntary standards or definitions. In October 2023, the ASTM F15.19 subcommittee submitted for administrative ballot F1519000223001 regarding Work Item WK81176—the AAP's position that "weighted" infant sleep products were not safe

and began to publicly recommend against the use of these (undefined and uncategorized) products.

83. The policy position from the CDC and NIH can be traced back to a statement by the AAP in its 2022 Technical Report.¹⁶ Exhibit 1, AAP 2022 Technical Report.

84. The CDC website states: “If you’re worried about your baby getting cold during sleep, you can dress them in sleep clothing. Options like a wearable blanket, also known as a sleep sack, are a safe alternative. Products labeled as weighted—including weighted sleepers, swaddles, sleep sacks, and blankets—are **not safe** or infants.”¹⁷ No research or scientific studies are cited to support this statement. Instead, the webpage simply states that “CDC supports the recommendations issued by the American Academy of Pediatrics (AAP) to reduce the risk of all sleep-related infant deaths. See How to Keep Your Sleeping Baby Safe: AAP Policy Explained to learn more about these and other actions.”

85. The referenced AAP webpage states that: “To reduce the risk of all sleep-related infant deaths, we revised our policy statement and technical report on safe sleep.” The AAP’s policy statement¹⁸ and technical report¹⁹ both “recommend[] that weighted blankets, weighted sleepers, or other weights not be placed on or near the sleeping infant[.]” But the only evidence for this position cited in AAP’s 2022 Technical Report was a single study that **did not recommend against the use of weighted sleepwear**. Ex. 1 at 20, 27, and n.327. Instead, that single study from 2020 (hereinafter “2020 NICU Study”) identified no adverse events; vital signs were stable throughout blanket use in the sixteen NICU infants that were observed; and the

¹⁶ AAP 2022 Technical Report, available at <https://tinyurl.com/24v5ws2t>.

¹⁷ Helping Babies Sleep Safely, CDC, (Sep. 25, 2024) <https://www.cdc.gov/reproductive-health/features/babies-sleep.html>.

¹⁸ AAP 2022 Policy, available at <https://tinyurl.com/3z5esd3y>.

¹⁹ AAP 2022 Technical Report, available at <https://tinyurl.com/3xepc72c>.

study's findings were "consistent with previous research that found no adverse events when weighted blankets or weighted vests were used[.]"²⁰ Exhibit 2, 2020 NICU Study at 388–89. Indeed, the 2020 NICU Study's "initial findings [were] that **weighted blankets may be beneficial ...**" *Id.* at 390 (emphasis added). However, the AAP's 2022 Technical Report recommended *against* "weighted" blankets, sleepers, and other products despite the 2020 NICU Study because "no studies have documented the safety of weights for infants in an unobserved, nonclinical sleep environment." Ex. 1 at 20. In other words, the recommendation of the AAP was not based on data, but on a lack of data; specifically, the lack of scientific peer reviewed data.²¹ The AAP fails to acknowledge that the lack of safety incidents attributed to Nested Bean products (despite selling more than 2.5 million units for over a decade) is in fact data and empirical evidence of their safety.

86. Likewise, the NIH Safe to Sleep® website states that "[t]hings in the sleep area can pose dangers for baby, especially if they are [w]eighted (e.g. weighted blankets, weighted swaddles)."²² Again, the only citation on this page is to the AAP's "technical report" referenced above, which again was based on nothing more than a misinterpretation of the 2020 NICU Study.

87. The NIH Safe to Sleep® website's Frequently Asked Questions asks, "Why are

²⁰ 2020 NICU Study, available at <https://gravite.fr/wp-content/uploads/2021/08/Weighted-Blankets-in-the-Care-of-Infants-With-Neonatal-Abstinence-Syndrome.pdf>.

²¹ As economist Dr. Emily Oster observed at the time the AAP revised guidelines were released, the AAP's "only evidence ... is a paper that demonstrated that weighted blankets could be used safely (and with some efficacy)," and "[t]o be clear: this paper is evidence of *safety*. There is no data cited suggesting danger." Emily Oster, *New AAP Guidelines on Breastfeeding and Safe Sleep: A case study in bad use of data*, ParentData (July 5, 2022), <https://parentdata.org/new-aap-guidelines-on-breastfeeding-and-safe-sleep/>.

²² Safe Sleep Environment for Baby, <https://safetosleep.nichd.nih.gov/reduce-risk/safe-sleep-environment> (last visited Oct. 17, 2025).

Weighted swaddles or blankets not recommended for babies?”²³ The answer, according to NIH, is because “[t]here is not enough evidence that weighted blankets and swaddles are safe to use” *Id.* In support, the NIH references the same 2020 NICU Study—which found that weighted blankets did not adversely affect infants and instead were beneficial—but conversely concluded that the safety of weighted blankets has not been proven. *Id.*

88. Finally, the NIH guidance, like the other agencies’ recommendations, relies on the same baseless advice from the CPSC and AAP.

89. In short, the Defendant-Agencies here base the at-issue guidelines on the AAP’s misinterpretation of the 2020 NICU Study and attempt to shore up their flimsy claims by relying on the baseless statements promulgated by one another to give an air of credibility to their imagined conclusions.

Conflating Soft Bedding with Weighted Sleep Products

90. Based on the Defendants’ reliance on the AAP 2022 Technical Report, Defendants are conflating the risks associated with soft, loose material in the sleep environment generally, with “weighted” sleepwear. This is an ecological fallacy—the risks of sleeping in a crib with soft bedding do not carry over to sleepwear.²⁴

91. Risks associated with sleepwear, regardless of weight, generally include suffocation and strangulation due to a baby’s head’s “submarining” into oversized neck openings, upward migration of the garment, scratching, and overheating.²⁵

²³ Frequently Asked Questions (FAQs), <https://safetosleep.nichd.nih.gov/reduce-risk/FAQ> (last visited Oct. 17, 2025).

²⁴ Compare AAP’s 2022 Technical Report citing seventeen different authorities for the statement that soft bedding can be hazardous when placed under the infant or left loose in the infant’s sleep area with the paucity of evidence related to “weighted” sleepwear. Ex. 1.

²⁵ CPSC Staff Comments to ASTM Committee, available at <https://tinyurl.com/tcvrxm6t>.

92. The CDC, NIH, and CPSC²⁶ do not recommend *against* the use of sleepwear generally; in fact, the CDC and NIH recommend *the use* of sleep sacks and wearable blankets as a safer alternative than soft bedding.²⁷

93. Likewise, the AAP website explaining AAP's policy on safe infant sleep states: “

If you're worried about your baby getting cold, you can dress them in layers of clothing or use a wearable blanket. In general, you should dress your baby in only one layer more than you're wearing. Don't use weighted blankets, sleepers, swaddles or other weighted objects on or near your baby.²⁸ (emphasis in original).

94. However, the AAP does not cite any study differentiating the safety of “weighted” vs. non-weighted sleepers and swaddles. Here, again, the AAP cites only the 2020 NICU Study, which found no adverse effects from the use of a “weighted” sleep product. Therefore, if sleep sacks are safe, “weighted” sleep sacks cannot be singled out as unsafe without evidence of such.

ASTM and CPSC 2023 Developments

95. Around March 2022, the ASTM F15.19 subcommittee initiated Work Item WK81176—Draft Standard Consumer Safety Specification for Wearable Blankets Intended for Use by Infants and Toddlers (“Draft Voluntary Standards”). The²⁹ ASTM Subcommittee F15.19 had been hard at work developing a voluntary safety standard for wearable infant blankets and

²⁶ See Infant Garments and Tight-fitting Sleepwear Garments, <https://www.cpsc.gov/FAQ/Infant-Tightfitting-Garments> (last visited Oct. 17, 2025).

²⁷ Helping Babies Sleep Safely, CDC, (Sep. 25, 2025) <https://tinyurl.com/yc42heyv> (“Options like a wearable blanket, also known as a sleep sack, are a safe alternative”); Ways to Reduce Baby’s Risk, <https://tinyurl.com/r59henet> (last visited Oct. 17, 2025). (“Dress baby in a wearable blanket or an extra layer of clothing to keep them warm without adding items to the sleep area.”).

²⁸ Rachel Y. Moon, MD, FAAP, *How to Keep Your Baby Safe: AAP Policy Explained*, <https://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/A-Parents-Guide-to-Safe-Sleep.aspx> (last visited Oct. 17, 2025).

²⁹ New Specification for Wearable Blankets & Swaddles Intended for Use by Infants and Toddlers, <https://www.astm.org/membership-participation/technical-committees/workitems/workitem-wk81176> (last visited Oct. 17, 2025).

swaddles alongside CPSC Staff since the subcommittee on Wearable Infant Blankets was formed one year prior. The subcommittee set out to provide performance standards for fit and construction as well as sizing and warnings to help address the potential hazard of suffocation resulting from a child slipping below the neck hole (known as “submarining”) in any wearable sleep product, regardless of weight.

96. In early 2023, the Office of Compliance and Field Operations (“Office of Compliance”), the compliance branch of the CPSC, conducted a four-month review of Nested Bean’s products to assess the risk of suffocation by the product potentially rising above infant’s nose and mouth, as this is a hazard pattern seen commonly across wearable infant sleep products. The valuation included, among other factors, a thorough assessment of the submitted products’ neck and arm hole measurements. Exhibit 3, Compliance Letter, dated April 5, 2023. After reviewing Nested Bean’s products, the Office of Compliance found no identifiable hazard patterns related to the risk of suffocation. *Id.* As such on April 5, 2023, the Office of Compliance sent Nested Bean a closing letter stating that no further action was warranted. *Id.* In other words, the CPSC’s own review of Nested Bean’s products showed no identifiable hazard related to suffocation.

70.97. In May 2023, CPSC staff reviewed the Draft Voluntary Standards and provided feedback to the ASTM F15.19 subcommittee. The CPSC staff rejected the suggested two years of reported incident data (January 1, 2011, through February 14, 2023) so the subcommittee could assess whether the performance requirements specific to weighted features “until additional research and testing and evaluation of the safety can be conducted.” in the Draft Voluntary Standard adequately addressed the hazard patterns in the incident data.³⁰

³⁰ Available at <https://tinyurl.com/tcvrxm6t>.

71. To date, CPSC has not promulgated any rules providing mandatory standards and definitions for products that could fall under the marketing category of weighted infant sleep products.

98. For its part, in a July 2023 meeting, Nested Bean gave CPSC staff detailed voluntary safety test data and related scientific research regarding its products. Exhibit 4, Nested Bean Letter to CPSC, dated August 7, 2023 (appendices omitted). Nested Bean's presentation and follow-up letter included evidence of the minimal weight (between thirty to ninety grams or one to three ounces) carefully embedded in its products and the products' careful designs, which avoid the risk of suffocation, overheating, and mobility restriction—all known risks based on ten years of publicly available safety incident data across wearable infant sleep products. *Id.*

99. In October 2023, the ASTM F15.19 subcommittee submitted a draft voluntary standard for wearable blankets to the CPSC. Work Item WK81176—Draft Standard Consumer Safety Specification for Wearable Blankets Intended for Use by Infants and Toddlers (“Draft Voluntary Standards”).³¹ These proposed standards included safety-enhancing performance requirements across all wearable sleep products. On October 2, 2023, the CPSC staff provided comments to the ASTM subcommittee on this proposal.³²

100. On October 11, 2023, during the CPSC Commission meeting to discuss the 2024 fiscal year operating plan (“FY ’24 Operating Plan Review Meeting”), CPSC’s Ex-Executive Director Jason K. Levine confirmed that CPSC staff wanted to include a “weighted infant sleep products” category in the broader ASTM voluntary standard being developed for all “wearable

³¹ New Specification for Wearable Blankets & Swaddles Intended for Use by Infants and Toddlers, <https://www.astm.org/membership-participation/technical-committees/workitems/workitem-wk81176> (last visited Oct. 17, 2025).

³² <https://tinyurl.com/3kpxmbcw>.

infant sleep products.”³³ Levine stated that adopting such a standard for the “weighted” category would be a safety improvement. *Id.* He further stated that, since there was no market consensus definition for “weighted” product, CPSC saw value in working with stakeholders to craft a definition to adequately address safety. *Id.* The Ex-Executive Director added that CPSC Staff did not have a position on AAP’s “weighted” products recommendation because all wearable sleep products have some weight. *Id.* But, he continued, CPSC staff was eager to work with the AAP to define “weighted” infant sleep products to further their safety. *Id.*

72.101. On November 8, 2023, the CPSC convened an internal meeting to discuss and potentially amend the upcoming Fiscal Year 2024 Operating Plan ~~Decisional and proposed amendments.~~ During this meeting, Commissioner Richard L. Trumka proposed an amendment to require CPSC “staff to initiate rulemaking and issue a proposed rule to address risks associated with weighted [sic] infant blankets, sleepers, and swaddles and align the Commission’s safe sleep~~Safe to Sleep~~ guidance and Centers for Disease Control (CDC) and National Institute of Health (NIH) guidance for weighted [sic] products.”³⁴

73.102. Commissioner Trumka’s proposed amendment was rejected by the Commission in a 3-1 vote. *Id.* In rejecting the proposal, Chairman Hoehn-Saric ~~expressed that it was explained~~ “[his] understanding that [CPSC] staff ha[d] not conducted the research necessary to draft a notice of proposed rulemaking in 2024,” and that “simply directing [the staff] to do it or wishing something to happen doesn’t reflect the work that has to go into a successful

³³ CPSC Commission Meeting FY ’24 Operating Plan Briefing (Oct. 11, 2023), available at <https://www.youtube.com/watch?v=Vj7d7gb4DFc&t=3630s>.

³⁴ CPSC, Minutes of Commission Mtg. 13 (Nov. 8, 2023), <https://perma.ee/U2P9-CHR4.> <https://www.cpsc.gov/s3fs-public/Comm-Mtg-Min-FY-2024-Operating-Plan-Decisional.pdf?VersionId=GDwWSUy29P7SN9MpqVVWdX5Nn9xe36Vm.>

rulemaking that ultimately reflects the science and can be sustained over time.”³⁵ The Chairman ~~went on to explain added~~ that “~~the~~ staff is very aware of the issue and working diligently to assess and quantify safety risks associated with weighted ~~[sic]~~ blankets.” *Id.* Commissioner Boyle and then-Commissioner Feldman ~~both~~ agreed that rulemaking “at this time [was] premature.” *Id.* at 21:52—22:05.

~~74. ASTM Committee F15.19 has been hard at work developing a voluntary safety standard for wearable infant blankets and swaddles alongside CPSC Staff; a subcommittee on Wearable Infant Blankets was formed, as F15.19, after a series of meetings in 2021. The subcommittee set out to provide performance standards for fit and construction as well as sizing and warnings to help address the potential hazard of suffocation resulting from a child slipping below the neck hole (known as “submarining”) in any wearable sleep product, regardless of weight. At the time of the 2023 CPSC meeting and well into 2024, the ASTM Committee F15.19 was, and still is, actively researching and analyzing hazard data on wearable infant sleep products in collaboration with CPSC Staff.~~

~~103. On November 16, 2023, the CPSC staff cast a negative vote against the F15.19(23-03) draft voluntary standard because it lacked specification about maximum weight limits for weighted wearable infant sleep products. In writing again to the ASTM F15.19 subcommittee regarding the Draft Voluntary Standard, the CPSC staff identified concerns sufficient to warrant voting against adoption of the proposed safety standard, because it did not have an “accompanying specification of maximum weight limits by age.” Staff noted the “lack of publicly available research relating to the issue at hand,” and thus undertook a “market scan of~~

³⁵ See CPSC, Commission Meeting FY24 Operating Plan Decisional 20:28–20:55 (Nov. 9, 2023), <https://perma.cc/AU4U-6HVB>.

~~non-weighted wearable blankets and swaddles as well as a range of products marketed as ‘weighted’ and made comparisons between the two groups.” The~~On November 16, 2023, CPSC staff reviewed ASTM’s Draft Voluntary Standards and provided additional feedback to the ASTM F15.19 subcommittee. Exhibit 5, CPSC Staff Letter and Market Survey, dated November 16, 2023. In general, CPSC staff agreed that the proposed standard would improve the safety of products within its scope by addressing common hazards across all wearable infant sleep products, such as disallowing hoods, requiring appropriately sized neck openings, and securing fasteners to limit the garment’s migration. *Id.* CPSC staff, however, rejected the suggested performance requirements because those proposed requirements included “weighted” infant blankets and swaddles without establishing maximum weight limits by age. Staff was concerned that without these limits, “a manufacturer could sell a wearable blanket or swaddle with an extremely heavy weight in it[.]” *Id.* CPSC staff encouraged ASTM members to review current research and information, and continue to conduct and share any research on “weighted” products. *Id.*

104. Included in the CPSC’s November 16, 2023, letter to ASTM was a CPSC-staff market survey. (“Market Survey”). Ex. 5. Staff noted that due to the “lack of publicly available research” relating to the issue of a maximum allowable weight limit the “staff [] collected and measured a variety of wearable blankets and swaddles marketed as weighted (“weighted”) and a variety of those products without any such marketing (“non-weighted”) currently sold on the market.”. *Id.* The staff found differences in the weight ~~concentration~~; some products ~~distributed~~ distributed the weight throughout the product, while others ~~concentrate~~ concentrated it in a specific area. *Id.* The staff also observed that ~~there was a number~~ many of the “non-weighted” products ~~that did not market themselves as~~

~~weighted but in fact weighed as much as some of, or more than, the “weighted” products.~~ *Id.*

105. While not explicitly stated in CPSC staff’s Market Survey, a comparison of Nested Bean’s product weight and the Market Survey revealed that Nested Bean’s products fell in the 25th–55th percentile for total weight among the 108 product samples considered. Notably, Nested Bean’s products were much lighter than many of the products that, although not labeled or marketed as “weighted,” contained filling meant to add warmth thus adding significant weight of the base product. *See Ex. 5.*

75.106. Based on reasons in the November 16, 2023, letter, CPSC staff cast a negative vote against the Draft Voluntary Standard on the ground that it lacked maximum weight limits for “~~weighted and some were heavier than other products marketed as weighted.”~~ wearable infant sleep products. *See Ex. 5* (explaining that the proposed safety standard did not have an “accompanying specification of maximum weight limits by age”). *Id.* The CPSC staff “encourage[d] the subcommittee to consider these observations and expand on the comparison between the two groups of products to establish a maximum weight limit that is proven to be safe for all products within the scope of the standard.” *Id.* Therefore, ~~the~~ “CPSC staff recommend[ed] that] the Subcommittee consider establishing weight concentration limits given existing scientific research, the differentiation CPSC staff observed, and NIH and CDC concerns about weighted blankets not being safe for infants.” *Id.*

CPSC Safe to Sleep® Guidelines

76.107. Sometime after the CPSC Operating Plan Decisional Meeting held on November 8, 2023,³⁶ the ~~CPSC’s website~~ CPSC modified ~~the~~ its Safe to Sleep Guidelines®

³⁶ At the Commission’s November 8, 2023, meeting to consider its Fiscal Year (FY) 2024 Operating Plan, then-Chair Hoehn-Saric noted that “[CPSC] staff is already working on how to

guidelines to recommend that the public not use an entire class of consumer products, “weighted” infant blankets and swaddles.³⁷ In theseThese guidelines, which remain on the CPSC states “CPSC’s website, state—in bold—“**Don’t use weighted blankets or weighted swaddles.”***” *Id.* Then, with a footnote, the CPSC deflects responsibility by asserting that statement is made with adding the caveat that “*This guidance is based on information from the Centers for Disease Control and the National Institutes for Health.” *Id.* In other words, consistent with then-Chair Hoehn-Saric’s statement at the Commission’s November 8, 2023, meeting, the CPSC admits that it has not conducted its own research or made its own determinations as to the safety of these products. The full notice on the website readreads as follows:

DON’T:

- **Don’t add pillows or blankets to your baby’s sleep space.**
- **Don’t use weighted blankets or weighted swaddles*.**
- **Don’t leave your baby unsupervised in products that aren’t designed for safe sleeping.** Inclined products with an angle greater than 10° -such as a rockers, gliders, soothers, and swings- *should never be used for infant sleep.*

*This guidance is based on information from the Centers for Disease Control and the National Institutes for Health. Please go to CDC.gov and NIH.gov for more information.

Id. (emphasis in original)

Commissioner Trumka’s 2024 Statements on Weighted Infant Sleep Products Vendetta

Against Nested Bean

108. Disregarding the lack of voluntary or mandatory standards; the lack of product

modify safe sleep guidance to account for the fact that both NIH and CDC is warning against the use of ... weighted wearables for infants” and that CPSC would be updating its guidance. CPSC Meeting Minutes, November 8, 2023, <https://perma.cc/U2P9-CHR4>. <https://www.cpsc.gov/s3fs-public/Comm-Mtg-Min-FY-2024-Operating-Plan-Decisional.pdf?VersionId=GDwWSUy29P7SN9MpqVVWdX5Nn9xe36Vm>.

³⁷ CPSC Safe Sleep Guidelines Cribs and Infant Products, available at <https://www.cpsc.gov/SafeSleep> (last accessed Nov. 27, 2024 visited Oct. 17, 2025).

category definitions; the lack of a product ban, stop sale, or recall;³² and the Commission's determination that CPSC~~it~~ lacked the necessary data to propose a mandatory standard on "weighted" infant sleepwear in fiscal year 2024, Commissioner Trumka chose to pursue a methodical negative publicity campaign against "weighted" infant sleep products ~~in through~~ public statements, national media interviews, social media posts, and ultimately letters to retailers,~~and social media posts.~~

77.109. On January 22, 2024, Commissioner Trumka sent Nested Bean a letter requesting exhaustive information about its product, quality control, safety research, health incidents, and safety messaging compliance. He demanded a response within two weeks—February 5, 2024. Nowhere in his letter did Commissioner Trumka inform Nested Bean that he was going to publicize statements about Nested Bean, the purported category of "weighted" infant sleep products, or the safety of these types of products. But before Nested Bean could respond, and only four days after sending the letter, Trumka posted an article on his official CPSC social media account that explicitly named Nested Bean.

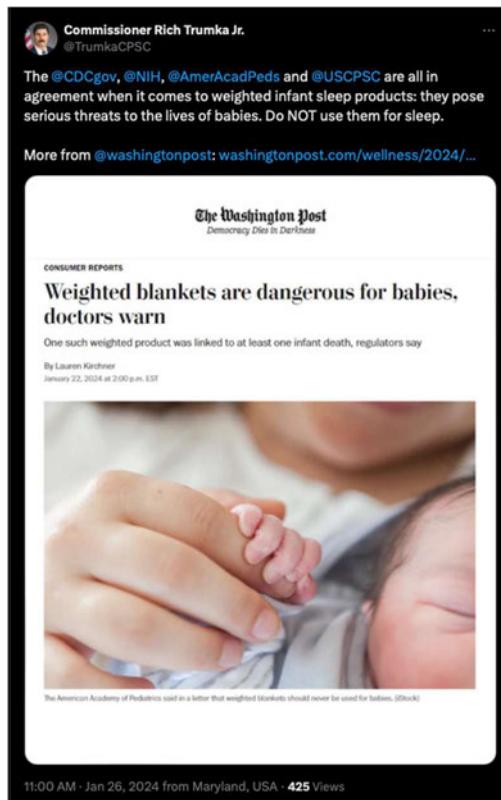
Commissioner Trumka's January 26, 2024 Statements

78.110. On January 26, 2024, Commissioner Trumka used his official CPSC X account (formerly Twitter)—@TrumkaCPSC—to post³⁸ a link to a Washington Post article naming Nested Bean explicitly in the second sentence.³⁹ The Exhibit 6, Washington Post

³⁸ @TrumkaCPSC, X.com (Jan. 26, 2024 at 1211:00 PMAM), <https://perma.cc/XQ9Z-NCJB>.

³⁹ Lauren Kirchner, Weighted blankets are dangerous for babies, doctors warn, Washington Post, January 22, 2024, available at <https://www.washingtonpost.com/wellness/2024/01/22/weighted-baby-blankets-unsafe/>, last visited January 10, 2025.

Article.⁴⁰ Trumka's post claimed that CPSC is "in agreement" with CDC, NIH, and the American Academy of Pediatrics that "weighted" infant sleep products "pose serious threats to the lives of babies,"⁴¹ and instructedwarned the public: "Do NOT use them for sleep." *Supra* note 17. A true and correct copy of the post is reproduced below:⁴¹



111. On February 16, 2024, Nested Bean responded to Trumka's January 22nd letter, explaining Nested Bean's safety record, product-development research, and involvement in the ASTM voluntary standards process. Nested Bean's thorough response included three empirical

⁴⁰ Lauren Kirchner, *Weighted blankets are dangerous for babies, doctors warn*, Washington Post, (Jan. 22, 2024), <https://www.washingtonpost.com/wellness/2024/01/22/weighted-baby-blankets-unsafe/>.

⁴¹ Commissioner Rich Trumka, Jr. (@TrumkaCPSC, X.com (Jan. 26, 2024 at 11:00 AM), available at <https://x.com/TrumkaCPSC/status/1750926680267333669>, last visited January 10, 2025.<https://perma.cc/XQ9Z-NCJB>.

studies it used for its product design and stated Nested Bean's ongoing willingness to share information about its products and meet with Commissioner Trumka as an important stakeholder. This information had already been provided to CPSC technical staff.

Commissioner Trumka's April 15, 2024 Statements

79.112. On April 15, 2024, ignoring Nested Bean's offer to meet, Commissioner Trumka sent identical letters on his official CPSC letterhead to seven major retailers, including Target, Walmart, Nordstrom, and Babylis^t, purportedly merely asking them to consider removing "weighted" infant sleepwear from their shelves (collectively "Stop Sale Letters"). In his letter heExhibit 7, Trumka Letter to Target, dated April 15, 2024; Exhibit 8, Trumka Letter to Walmart, dated April 15, 2024; Exhibit 9, Trumka Letter to Nordstrom, dated April 15, 2024; Exhibit 10, Trumka Letter to Babylis^t, dated April 15, 2024. In these letters, he again cited directly to the *Washington Post* article that named Nested Bean in its second sentence^s and Trumka claimed that "multiple infant deaths" had been linked to "weighted" sleepwear products.

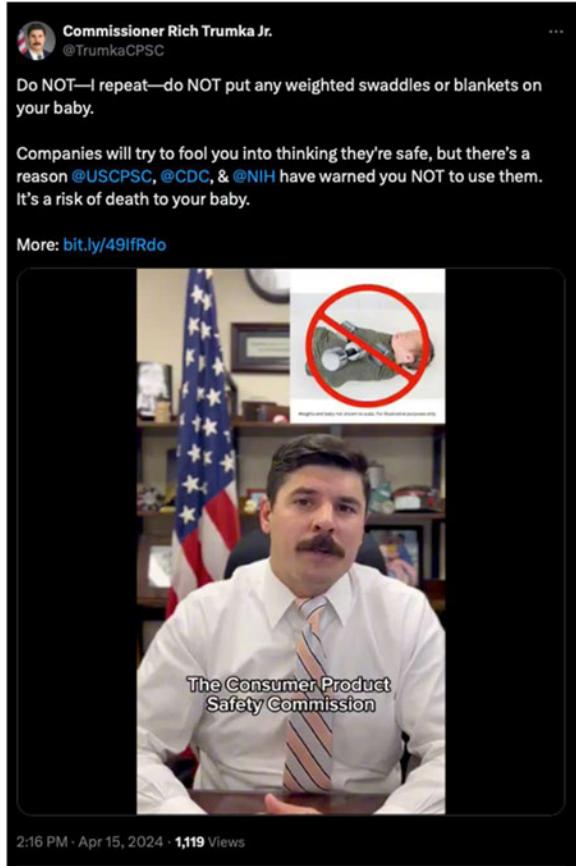
See Ex. 6.

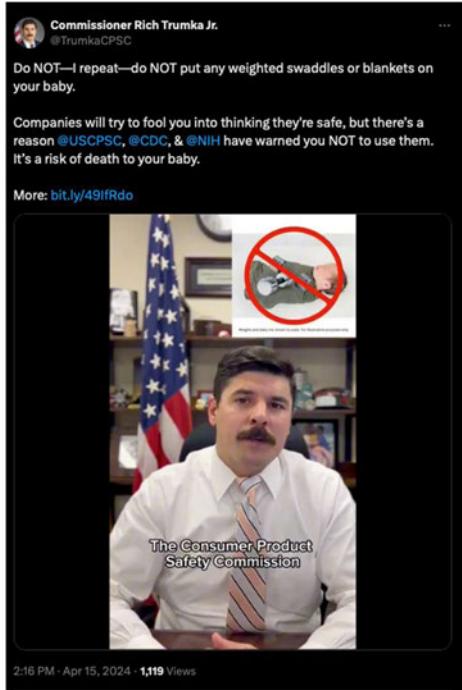
80.113. On the same day, Commissioner Trumka posted a video on Xhis official CPSC X account⁴² and on his official CPSC Instagram⁴³ account⁴⁴ each with a caption stating "Do NOT – I repeat – do NOT put any weighted [sic] swaddles or blankets on your baby. Companies will try to fool you into thinking they're safe, but there's a reason @USCPSC, @CDC, & @NIH have warned you NOT to use them. It's a risk of death to your baby." *Id.* The video-also included an intentionally dramatized photo showing a baby with metal dumbbells on its chest. Screenshots of the April 15, 2024, posts on X and Instagram are reproduced below.

⁴² @TrumkaCPSC, X.com (Apr. 15, 2024 at 3:16 PM), https://perma.cc/G86U-C3ZY.

⁴³ @trumkaepse, Instagram.com (Apr. 15, 2024), https://perma.cc/MM4F-ZL8V.

⁴⁴ @trumkacpsc, Instagram.com (Apr. 15, 2024), https://perma.cc/MM4F-ZL8V.





2:16 PM - Apr 15, 2024 • 1,119 Views



81.114. In the videos Trumka states:

It seems like a new baby product comes on the market every day. Some new ones that you need to watch out for are *weighted [sic] infant swaddles and blankets*. Weighted [sic] blankets for adults are one thing, but they have no place in infant sleep. The Consumer Product Safety Commission just updated our safe sleep guidance to warn you NOT to use these products with your babies. This brings us in line with NIH and CDC which warns that *weighted [sic] products are unsafe for infants*. And when unsafe comes up in the infant sleep space, let's be clear we're talking about the *risk of death*. You can find our safe sleep guidance at cpsc.gov/safesleep. It has great information on what to do and what not to do.

Id. (emphasis added).

82.115. That same day, April 15, 2024, CPSC posted Trumka's statement on its website entitled: *Beware: Weighted [sic] Infant Swaddles and Blankets are Unsafe for Sleep; Retailers Should Consider Stopping Sales.*⁴⁵ [Exhibit 11, Trumka Statement, dated April 15,](#)

⁴⁵ [Comm'r Trumka, Beware: Weighted Infant Swaddles and Blankets Are Unsafe for Sleep; Retailers Should Consider Stopping Sales \(Apr. 15, 2024\), available at https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Beware-Weighted-Infant-Swaddles-and-Blankets-Are-Unsafe-for-Sleep-Retailers-Should-Consider-Stopping-Sales](https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Beware-Weighted-Infant-Swaddles-and-Blankets-Are-Unsafe-for-Sleep-Retailers-Should-Consider-Stopping-Sales), last visited January 10, 2025.

2024.⁴⁶ Trumka's Statement again cited to the Washington Post article that named Nested Bean. See Ex. 6. The statement purported to speak on behalf of CPSC stating that the full Commission: "CPSC has a clear warning for safe infant sleep: Don't use weighted [sic] blankets or weighted [sic] swaddles for your babies." *Id.* (emphasis in original). The Ex. 11. Trumka's statement also alleges alleged, without any citation to proof, that "There are multiple infant deaths in these products." *Id.* And it told retailers that "we do not have to wait for a federal rule,"⁴⁷ and that they the Commissioners have "the power to stop sales" and "take precautions today." *Id.* (emphasis added). The CPSC statement page also which remains live on the CPSC website contains a link to Commissioner Trumka's April 15, 2024 statement, video on X, as mentioned *supra*. This statement was published on CPSC's official website, and Commissioner Trumka signed his statement, "Your consumer advocate at the Consumer Product Safety Commission." *Id.*

116. On April 19, 2024, representatives from Target emailed Nested Bean in response to "the new CPSC warning that was issued about weighted [sic] swaddles this week," expressly referencing Commissioner Trumka's April 15th statement by hyperlink, and they asked Nested Bean to meet with Target's general counsel, compliance and safety/quality/regulatory partners to discuss the safety of Nested Bean's products "based on" Commissioner Trumka's statement.

117. On April 22, 23, and 25, 2024, Commissioner Trumka met with Target representatives multiple times to discuss Target's response to his April 15th letter recommending Target stop the sale of "weighted" infant sleep products.⁴⁷

⁴⁶ Comm'r Richard Trumka, *Beware: Weighted Infant Swaddles and Blankets Are Unsafe for Sleep; Retailers Should Consider Stopping Sales* (Apr. 15, 2024), <https://tinyurl.com/56nzcah4>.

⁴⁷ Log of April 22, 2024 Meeting, Office of Commissioner Trumka, <https://tinyurl.com/bdzur24r>; Log of April 23, 2024 Meeting, <https://tinyurl.com/5hdhnmyu>; Log of April 25, 2024 Meeting, <https://tinyurl.com/39z236vz>.

118. On April 25, 2024, after a Zoom meeting with Nested Bean, Target informed Nested Bean that “after much internal review” it would no longer sell any of Nested Bean’s products, and that the products would “be removed from our stores and online by the end of the week.” Prior to Trumka’s April 15th letter, Nested Bean had just been awarded in March 2024 an expanded footprint across over 1200 stores of the prestigious national retail chain, after years of working successfully with the major retailer. However, after this swift decision that took less than one week, Target proceeded to remove all inventory from over 1200 of its stores.

119. By April 23, 2024, Amazon too stopped sales of all Nested Bean products and notified customers who had purchased Nested Bean products in the past twelve months that CPSC had “warned that these products should not be considered safe for use by children and babies.” One such email is reproduced below.

----- Forwarded message -----
From: Amazon Product Safety Team <order-update@amazon.com>
Date: Tue, Apr 23, 2024 at 10:39AM
Subject: Attention: Important safety notice about your past Amazon order
To: [REDACTED]



Dear Amazon Customer,

Our records indicate that you purchased a weighted infant sleep product from us in the last 12 months.

Affected Product: B09JKYSDJG - Nested Bean Zen One® | Infant Swaddle | Babies 0-3M (7-13 Lbs) | Adapts for Arms In/Out | Prevents Startles | Aids Self-Regulation | 2-Way Zipper | TOG 1.0 | Machine Washable
Order ID: 114-3029808-5010654

The American Academy of Pediatrics (AAP) and Consumer Protection and Safety Commission (CPSC) have warned that these products should not be considered safe for use by children and babies. You can find more information on safe infant sleep in this CPSC alert: <https://www.cpsc.gov/SafeSleep>.

If you still have any of these products, we recommend you stop using these products for children and infants under three years old. If you purchased this item for someone

else, please notify the recipient immediately and provide them with the information contained within this message.

Please contact Amazon Customer Service if you have any additional questions.

The safety and satisfaction of our customers is our highest priority. We regret any inconvenience this may cause you.

Thanks for shopping at Amazon.

Sincerely,
Customer Service
Amazon.com
www.amazon.com

Please note: this e-mail was sent from a notification-only address that cannot accept incoming e-mail. Please do not reply to this message.

©2024 Amazon.com, Inc. or its affiliates. Amazon and all related marks are trademarks of Amazon.com, Inc. or its affiliates, Amazon.com, Inc. 410 Terry Avenue N., Seattle, WA 98109.



Commissioner Trumka's April 26, 2024 Statements

83.120. On April 26, 2024, Commissioner Trumka made another statement on the CPSC website,⁴⁸ his official CPSC X account,⁴⁹ and his official CPSC Instagram account,⁵⁰ gloating about the harm he was able to do to Plaintiff's inflicted on Nested Bean's business while skirting procedural requirements through his rogue actions. Exhibit 12, Trumka Statement, dated

⁴⁸ Trumka Statement, April 26, 2024, available at https://www.epsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Target-Walmart-Nordstrom-and-Babylist-Commit-to-Stop-Selling-Weighted-Infant-Products#_ftnref1, last visited January 10, 2025.
Comm'r Richard Trumka, Target, Walmart, Nordstrom, and Babylist Commit to Stop Selling Weighted Infant Products, (Apr. 26, 2024), <https://tinyurl.com/bdz3tyvn>.

⁴⁹ @TrumkaCPSC, X.com (Apr. 26, 2024 at 10:26 AM), <https://perma.cc/4CGR-8VWB>.

⁵⁰ @trumkacpsc, Instagram.com (Apr. 26, 2024), <https://perma.cc/EL23-JDLV>.

April 26, 2024. The statement reads, in part, “On April 15, 2024, I wrote to major U.S. retailers informing them of the hazards weighted [sic] infant swaddles and blankets pose to babies, and asking them to consider whether they want to continue selling such products. I am pleased to announce that Target, Walmart, Nordstrom, and Babylist quickly responded by sharing that they will cease sales of weighted [sic] infant products” and “I expect to hear back from additional retailers soon.” *Id.* Screenshots of the April 26, 2024, posts on his official CPSC X and Instagram accounts are reproduced below.





84.121. In his videos Trumka states:

I have some great news to report. Last week, I wrote to major U.S. retailers and I wanted to talk to them about a product category that I'm concerned about: Weighted [sic] infant blankets and swaddles. I wanted to let them know that CPSC, CDC, NIH, and the American Academy of Pediatrics have all warned against their use and that multiple deaths have occurred in these products. Armed with this information, multiple major U.S. retailers decided to stop selling these products out of an abundance of caution and a mind toward safety. And I wanted to take time to commend those companies. Target, Walmart, Nordstrom, Amazon, and Babylist all made the decision to pull sales of these products. I have letters out to other retailers as well; I haven't heard back from them quite yet. I'm gonna report to you when I do. Stay safe.

Id.

ResponsesHarm to Nested Bean as a Result of Statements of Commissioner Trumka and the Commission

85.122. Defendants' statements resulted in direct harm to Plaintiff's Plaintiff's business. Multiple major retailers, including Target, Amazon, and others discontinued the sale of Nested Bean products in response to Defendants' misleading statements.

86.123. Most of these retailers keptcontinued to sell other brands of "weighted" infant sleep products that were not mentioned in Trumka's letters available for sale on their

platforms.

87. — Amazon stopped sales of Nested Bean's products and notified customers who had purchased Nested Bean products in the past 12 months that CPSC had "warned that these products should not be considered safe for use by children and babies."

88.124. — As a result, Nested Bean has experienced a greater Bean's sales have dropped more than 80% reduction in sales, forcing the layoff of %, and it was forced to lay off 93% of its workforce. This devastating decline has ruined Nested Bean's relationship with leading Bean's relationships in the retail partners and is risking the company's future industry, including several independent retailers that have followed suit and stopped carrying Nested Bean products in their stores. Nested Bean's survival and ability to bring effective products to help its customers, which also risks are at risk, as is its ability to as a knowledgeable manufacturer to participate in the ASTM standards creation as a knowledgeable manufacturer to for the benefit the industry as a whole.

89. — On January 22, 2024, Commissioner Trumka sent Nested Bean a letter requesting that it provide information about its product, quality control, safety research, health incidents, and safety messaging compliance by February 5, 2024. But before Nested Bean could respond, and only four days after sending the letter, Trumka posted an article on social media that explicitly named Nested Bean, as discussed above. On February 16, 2024, Nested Bean provided responses to Commissioners Trumka, Hoehn-Saric, Boyle, and Feldman explaining Nested Bean's safety record, research into the product development, and involvement in the ASTM voluntary standards process.

90.125. — On May 22, 2024, Nested Bean wrote to Commissioner Trumka, to ask and asked him to correct the record regarding his attacks on the company by issuing and issue an

immediate retraction of his inaccurate and misleading statements. On July 22, 2024, Commissioner Trumka ~~responded by refusing to retract his statements by refused and~~ falsely ~~claimingclaimed~~ that they were his personal statements, even though they were made from his official letterhead ~~and~~, on his official social media ~~aceoantaccounts~~, and posted to the CPSC website. ~~And he without any “personal statement” disclaimer. He~~ tried to shirk his statutory responsibilities by relying on the equally unsupported statements of other health agencies that are *not* tasked with product safety and ~~elaimedclaiming~~ that he merely echoed the warnings of CPSC in his “personal” statements.

91.126. This wasn't the first time that Commissioner Trumka has abused his power. On July 25, 2024, the Chairman of the House Committee on Small Business announced that it was launching an investigation into Trumka's unilateral actions and abuse of power, specifically pertaining to the very actions that Nested Bean is complaining about.⁵¹ This investigation ~~is a result of~~results from a pattern of Trumka exceeding his regulatory authority by repeatedly going rogue and issuing public statements about a product under the guise of official CPSC authority.⁵² For example, in January ~~ef~~ 2023, Trumka ~~made public statementsannounced to the world~~ that the CPSC intended to ban gas stoves.⁵³ ~~The gas stove debacle was very similar to this situationAs in that the CPSC had declined~~Nested Bean's case, in which Trumka ignored

⁵¹ Congressional Small Business Committee letter to CPSC Chairman, dated July 25, 2024, <https://perma.cc/NVR2-MNHW>.

⁵² Zack Halaschak, GOP panel accuses safety commission's Richard Trumka Jr. of pressuring private businesses, Zack Halaschak, Washington Examiner (July 25, 2024, available at), <https://www.washingtonexaminer.com/news/business/3098110/gop-panel-accuses-safety-commissions-trumka-jr-pressuring-private-businesses/#google%20vignette>.

⁵³ Breanne Deppisch, Gas stove ban not in the works, agency chairman says amid uproar, Breanne Deppisch, January Washington Examiner (Jan. 11, 2023, available at), <https://www.washingtonexaminer.com/news/405289/gas-stove-ban-not-in-the-works-agency-chairman-says-amid-uproar.>

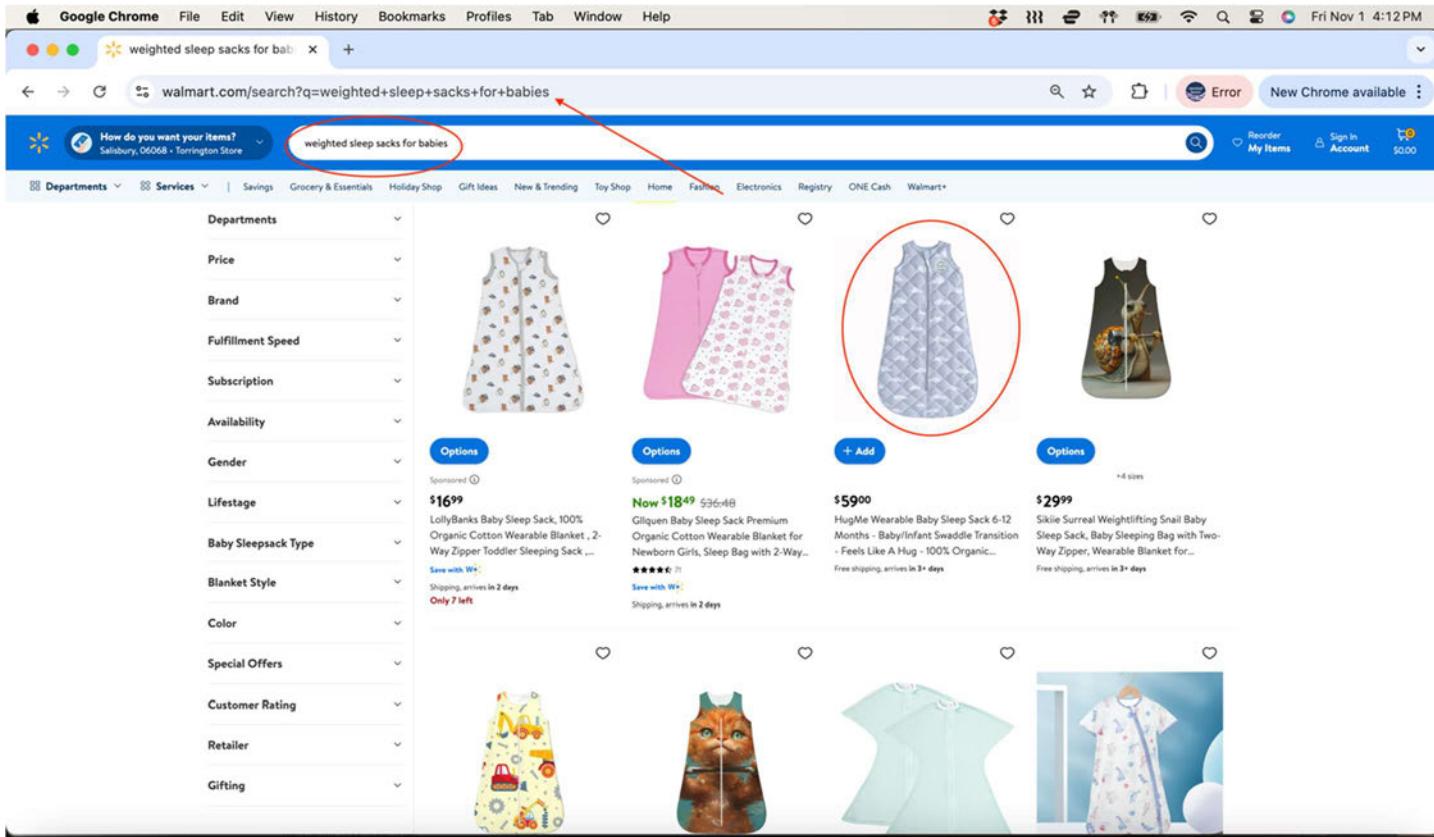
the CPSC's decision not to adopt Trumka's initiate rulemaking for "weighted" products, Trumka followed the CPSC's decision against proposed gas-stove standards for gas stoves—yet, without any CPSC authority, he publicly stated that the CPSC was going to ban gas stoves with a rogue media campaign.⁵⁴ This statement was so inaccurate and misleading, and caused such a public backlash, that the Chairman for the CPSC felt it necessary to issue his own statement clarifying that the Commission was not intending had no intention to ban gas stoves.⁵⁵

92.127. On August 1, 2024, Nested Bean again wrote to Commissioner Trumka and demanded that he immediately retract the inaccurate and misleading statements. Nested Bean's letter provided evidence that his letters Stop Sale Letters to retailers telling them to not to sell weighted sleep products, which cited the Washington Post article that expressly named Nested Bean and one other company, resulted in caused most retailers only taking down to stop selling their products of the two companies named in the article. Retailers were still selling continued to sell "weighted" sleep products from unnamed manufacturers, just not Nested Bean. Trumka's August 16, 2024 response ignored the retraction request that Trumka did not name through his official CPSC platforms. See example below.

On

⁵⁴ Breanne Deppisch, The obscure regulator (and political scion) who sparked the furor over gas stoves, Breanne Deppisch, January Washington Examiner (Jan. 12, 2023, available at) <https://www.washingtonexaminer.com/news/2277854/the-obscure-regulator-and-political-scion-who-sparked-the-furor-over-gas-stoves/>.

⁵⁵ Chair Alexander Hoehn-Saric, Statement of Chair Alexander Hoehn-Saric Regarding Gas Stoves, January (Jan. 11, 2023, available at) <https://www.cpsc.gov/About-CPSC/Chairman/Alexander-Hoehn-Saric/Statement/Statement-of-Chair-Alexander-Hoehn-Saric-Regarding-Gas-Stoves>.



56

128. Trumka's August 2616, 2024, response ignored the retraction request.

Nested Bean Seeks Retraction of CPSC and Commissioner Trumka's Statements

129. ASTM F15.19 subcommittee released report "ASTM F15.19 Data Analysis Task Group Wearable Infant Blanket Related Incident Data."⁵⁷ ASTM completed On November 11, 2024, and pursuant to 15 U.S.C. § 2055(b)(7) (Section (b)(7)), counsel for Nested Bean sent a Hazard Analysis using letter to the Secretary of the Commission seeking a Section 6(b)(7) retraction of the inaccurate and misleading statements by Commissioner Trumka and by the

⁵⁶ Image depicts the results of a search of Walmart products for weighted sleep sacks for babies as of November 1, 2024. <https://www.walmart.com/search?q=weighted+sleep+sacks+for+babies> (last visited Oct. 17, 2025).

⁵⁷ CPSC and ASTM F15.19 Wearable Infant Blankets Data Analysis and Performance Requirements Task Force Meeting Log, Aug. 26, 2024, <https://perma.cc/JWN6-LT3H>.

CPSC itself (“Retraction Request”).⁵⁸

130. The Retraction Request asked the CPSC to publicly retract (a) Commissioner Trumka’s inaccurate and misleading statements, as detailed *supra*, and (b) the CPSC’s data on safety incidents involving various Safe to Sleep® recommendation against the use of “weighted” infant sleep products from various manufacturers. *Id.* The Retraction Request provided in detail the legal and factual bases for the request. *Id.*

131. Around December 19, 2024, the Commission voted on, and denied, Nested Bean’s request for retraction.⁵⁹ found that thereThe outcome of the vote was no unique hazard pattern associated0-1-1-2 with zero commissioners voting for the retraction, one and one representing separately proposed courses of action, and two representing abstentions. *Id.* Commissioner Trumka recused himself from the vote. *Id.* Chairman Hoehn-Saric proposed delaying a response for ninety days to allow the CPSC more time to consider all the facts and circumstances. *Id.* Commissioner Boyle proposed (1) sending a letter to retailers clarifying that the Commission has not taken any official action and that Commissioner Trumka’s statements were not made on behalf of the CPSC and do not constitute a stop sale, ban, or recall; and (2) directing the CPSC staff to review the Safe to Sleep® guidance in light of new information since its posting in 2023. *Id.* Commissioners Feldman and Dziak abstained from the vote and issued a joint statement suggesting that Nested Bean’s relief is “best obtained through an Article III

⁵⁸ Demand Letters to the Consumer Product Safety Commission on Behalf of Nested Bean, Liberty Justice Center, <https://libertyjusticecenter.org/other-legal-work/demand-letter-to-cpsc-on-behalf-of-nested-bean/> (last visited Oct. 17, 2025) (Nested Bean’s November 11, 2024 Letter to CPSC).

⁵⁹ https://www.cpsc.gov/s3fs-public/RCA-Request-by-Nested-Bean-Inc-for-Retraction-of-Information-Pursuant-to-Section-6b-7-of-the-Consumer-Product.pdf?VersionId=7WeplZFMBCL7w_DcA.7ukgp_WInt2t3.
<https://tinyurl.com/4v2mmtht>.

court.”

132. Recently, sometime between August 28, 2025, and September 2, 2025, the Safe to Sleep® guidelines that recommended against using “weighted” infant sleep products, were inexplicably removed from the CPSC’s website. See reproduced webpage below.

The screenshot shows a web browser capture of the CPSC website. The URL is https://www.cpsc.gov/SafeSleep. The page title is "Safe Sleep – Cribs and Infant Products". The main content features a large image of a baby sleeping peacefully. Below the image, a section titled "Make Sure Baby Has a Safe Sleep Space" provides tips for safe sleep, including using a crib, bassinet, or play yard that meets federal standards, placing the baby on their back, and checking for recalls. A sidebar on the right offers a "Report an unsafe product" option. The page also includes navigation links for recalls, safety education, business & manufacturing, laws, regulations, research, and about the commission.

93.133. Then, as quickly and inexplicably as the recommendation disappeared, on approximately September 5, 2025, the recommendation against “weighted” *Id.* The report demonstrated that a combination of hazardous behavioral sleep practices were typically present in each reported fatality case, including swaddling past rolling age, co-sleeping, in-line, soft bedding, use of products that have since been banned, and leaving a bottle unattended for an

extended period—all proven unsafe practices. *Id.* reappeared on the CPSC website, and remains on the website as of the date of the filing of this First Amended Complaint.

94.134. The injury to Nested Bean is ongoing as because Commissioner Trumka's statements and the Safe to Sleep Guidelines® guidelines remain posted on the Commission's public facing website and because the Commission has declined to retract or correct the statements. Commissioner Trumka's disparaging posts on official CPSC X and Instagram accounts also remain visible to the public.

95.135. Nested Bean was not provided notice of any of Commissioner Trumka's statements before they were made public, even though the statements allow the public to readily ascertain Nested Bean's identity.

96.136. On information and belief, retailers were misled by Commissioner Trumka's letter and communications into believing that the CPSC had made a product safety determination regarding "weighted" infant sleep products when the Commission had made no such determination and, in fact, when the Commission admittedly lacked data or evidence supporting such an action.

97.137. As a result of Commissioner Trumka's actions, Nested Bean has suffered and continues to suffer significant reputational and economic harm, including retailersretailers' stopping sale of its products.

Nested Bean Seeks Retraction of CPSC and Commissioner Trumka's Statements

98. On November 11, 2024, and pursuant to 15 U.S.C. § 2055(b)(7), counsel for Nested Bean sent a letter to the Secretary of the Commission seeking a Section 6(b)(7) request for retraction of the inaccurate and misleading statements by Commissioner Trumka and the

CPSC (“Retraction Request”).⁶⁰

99.1. The Retraction Request asked the CPSC to publicly retract Commissioner Trumka’s inaccurate and misleading statements, as detailed *supra*, and retract the provision of the CPSC’s Safe Sleep Guidance that advocates *against* the use of weighted infant sleep products. *Id.* The Retraction Request also provided in detail the legal and factual basis for the request. *Id.*

100.1. Around December 19, 2024, the Commission voted on, and denied, Nested Bean’s request for retraction.⁶¹ The outcome of the vote was 0 1 1 2 with 0 commissioners voting for the retraction, 1 and 1 representing separately proposed courses of action, and 2 representing two abstentions. *Id.* Commissioner Trumka recused himself from the vote. *Id.* Chairman Hoehn-Saric proposed delaying a response for 90 days to allow the CPSC more time to consider all the facts and circumstances. *Id.* Commissioner Boyle proposed (1) sending a letter to retailers clarifying that the Commission has not taken any official action, and that Commissioner Trumka’s statements were not made on behalf of the CPSC and do not constitute a stop sale, ban, or recall; and (2) directing the CPSC staff to review the Safe Sleep Guidance in light of new information since its posting in 2023. *Id.* Commissioners Feldman and Dziak abstained from the vote and issued a joint statement suggesting that Nested Bean’s relief is “best obtained through an Article III court.”

CLAIMS FOR RELIEF

Count One

⁶⁰ Nested Bean’s November 11, 2024 Letter to CPSC, <https://libertyjusticecenter.org/other-legal-work/demand-letter-to-cpsc-on-behalf-of-nested-bean/>.

⁶¹ https://www.cpsc.gov/s3fs_public/RCA_Request_by_Nested_Bean_Inc_for_Retraction_of_Information_Pursuant_to_Section_6b_7_of_the_Consumer_Product.pdf?VersionId=7WeplZFMBCL7w_DeA.7ukgp_WInt2t3. <https://tinyurl.com/4v2mmtht>.

**Violation of the Administrative Procedure Act Excess of Statutory Authority
(Against CPSC)**

101-138. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

102-139. Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law” or ~~is~~ “in excess of statutory ~~.....~~ authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

140. To determine when an agency action is final, we have looked to, among other things, whether its impact “is sufficiently direct and immediate” and has a “direct effect on ... day-to-day business.” *Abbott Laboratories v. Gardner*, 387 U.S. 136, 152 (1967). The core questions are whether the agency has completed its decision-making process and whether the result of that process is one that will directly affect the regulated party. *See Franklin v. Massachusetts*, 505 U.S. 788, 796–97 (1992).

141. In a series of successive actions, each can be a final agency action in its own right. *See Biden v. Texas*, 597 U.S. 785, 808–09 (2022).

142. The issuance of public statements by an agency advocating for or against a particular action by the public are final agency actions subject to judicial review. *See Apter v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023).

143. The CPSC decision to publish the Safe to Sleep ~~Guidance®~~ guidance advocating against the use of ~~all~~ “weighted” infant sleep products is a final agency action under the APA;
the CPSC’s decision not to retract the statements is a separate final agency action.

103-144. The CPSA does *not* provide the Commission discretion to adopt the consumer product safety determinations made by other agencies without following the CPSA

procedures and requirements. The Commission's authority is to protect against unreasonable risks of injury or death.

~~104.~~—The CPSA provides the framework for determining whether consumer products present an unreasonable risk of injuries. The CPSC may only injury. Before the Commission can promulgate rules, a mandatory ~~consumer product~~ safety standard, in accordance with 15 U.S.C. § 2058, that is “reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product.” 15 U.S.C. § 2056(a).

~~105.~~—The Commission may promulgate a rule banning a hazardous product, in accordance with 15 U.S.C. § 2058, but may only do so after finding that the consumer product presents an unreasonable risk of injury and there is “no feasible consumer product standard under this Act [that] would adequately protect the public from the unreasonable risk of injury associated with such product[.]” 15 U.S.C. § 2057.

~~106.~~145.—The promulgation of a consumer product safety rule, including both a mandatory standard and a product ban, it must follow the procedural requirements of 15 U.S.C. § 2058, which includes, among other things, the requirement to identify the degree and nature of the risk of injury associated with the product and how the proposed action is reasonably necessary and is designed to eliminate or reduce the risk of injury. See 15 U.S.C. § 2058. The Commission may promulgate a mandatory consumer product safety standard, in accordance with 15 U.S.C. § 2058, only if it is “reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product.” 15 U.S.C. § 2056(a). The Commission can only ban a product if (1) there is an unreasonable risk of injury and (2) there is no product safety standard that can protect against the risk. 15 U.S.C. § 2057. See 15 U.S.C. § 2058

146.—The Commission must also “conduct a ‘final regulatory analysis’—*i.e.*, a cost-benefit analysis—before promulgating a safety standard. The analysis must detail costs, benefits,

and alternatives to the proposed standard, and must address any issues raised by commenters.”

Window Covering Mfrs. Ass’n v. CPSC, 82 F.4th 1273, 1279 (D.C. Cir. 2023) (citing 15 U.S.C. § 2058(f)(2)). The Commission must also make a “host of findings” before promulgating a rule, which must be supported by data and evidence. Finnbin, LLC v. CPSC, 45 F.4th 127, 131 (D.C. Cir. 2022) (citing 15 U.S.C. § 2058(f)).

107-147. The CPSA requires the Commission to establish procedures to ensure that the information it publicly releases that reflects on the safety of a consumer product or class of consumer products is accurate and not misleading. *See* 15 U.S.C. § 2055.

108. In order to promulgate a mandatory safety standard, the Commission must first determine the risk of injury then “express in the rule itself the risk of injury which the standard is designed to eliminate or reduce.” *Id.* In doing so, the Commission must “consider relevant available product data including the results of research, development, testing, and investigation activities conducted generally and pursuant to [the CPSA].” 15 U.S.C. § 2058(e).

109. The Commission must also “conduct a ‘final regulatory analysis’ – i.e., a cost benefit analysis – before promulgating a safety standard. The analysis must detail costs, benefits, and alternatives to the proposed standard, and must address any issues raised by commenters.” Window Covering Mfrs. Ass’n v. CPSC, 82 F.4th 1273, 1279 (citing 15 U.S.C. § 2058(f)(2)). There must also be a “host of findings” the Commission must make before promulgating a rule, many of which must be supported by data and evidence. Finnbin, LLC v. CPSC, 45 F.4th 127, 131 (D.C. Cir. 2022) (citing 15 U.S.C. § 2058(f)).

110. The CPSA also permits the Commission to ban hazardous products which present “an unreasonable risk of injury[.]” 15 U.S.C. § 2057. Banning a product requires the Commission to “find that the product at issue presents an unreasonable risk of injury and that no feasible safety standard would adequately protect the public from it. In banning products, the

~~CPSC must follow the procedures that govern its general power to promulgate safety standards.”~~
~~Finnbin, 45 F.4th at 131 (citing 15 U.S.C. § 2057).~~

¶111. The CPSA does *not* provide the CPSC the discretion to adopt the consumer product safety determinations made by other agencies without following the CPSA procedures and requirements.

¶112-148. The Commission’s Safe to Sleep Guidance® guidance regarding “weighted” infant sleep products is a product safety determination.

¶113-149. ~~The~~On information and belief, the Commission took none of the required steps before it adopted and repeated CDC’s and NIH’s unsupported product safety determinations regarding “weighted” infant sleep products.

¶114-150. The product safety determination made by CPSCCommission regarding “weighted” infant sleep products was not authorized by statute and thus exceeds CPSC’s sits authority under CPSA, which carefully outlines how and when CPSCCommission may regulate consumer products or make determinations about a product’s safety. The CPSA does not authorize CPSCCommission to determine the safety of consumer products absent evidence and data.

¶115-151. Accordingly, CPSC’s Safe to Sleep Guidance® guidance is a product safety determination that was “not in accordance with” or “in excess of” its statutory authority because it opines on the safety of weighted infant sleep products and directs parents and caregivers not to use weighted infant sleep products. 5 U.S.C. § 706(2)(A), (C)

¶116-152. Likewise, CPSC’s the Commission’s December 2024 decision to not to remove its Safe to Sleep Guidance® guidance and its decision to take no action with respect to

Commissioner Trumka's statements ~~was~~were also made "in excess of" CPSC's statutory authority. 5 U.S.C. § 706(2)(C).

153. The CPSC's publication of the Safe to Sleep® guidelines advocating against "weighted" infant sleep products violates the requirements of 15 U.S.C. § 2055(b)(1) and (6) because the statements are inaccurate and misleading, and the CPSC failed to provide the required notice to readily ascertainable manufacturers

154. The CPSA requires that the Commission ensure that public disclosures are "accurate and not misleading." 15 U.S.C. § 2055(b)(6). But the CPSC's Safe to Sleep® guidance advocating against "weighted" infant sleep products is inaccurate and misleading because it fails to comport with the requirements of § 2055(b)(6). Directive 1450.2 sets out the required clearance procedures to ensure disclosures are accurate and not misleading.

155. On information and belief, the Commission failed to adequately adhere to the clearance procedures of Directive 1450.2 when it published its Safe to Sleep® guidance.

156. The technical and scientific clearance requires support from:

(a) data in commission files or in currently applicable literature; (b) articulated technical judgment that is both reduced to writing and based on consideration of all relevant factors; or (c) a report prepared by a contractor to the Commission and such report has been subject to a review process by Commission staff.

Id. The Safe to Sleep® public guidance was issued without conducting these safety evaluations or research specific to "weighted" infant sleep products.

157. If the CPSC had in its possession "information as to any significant risk associated with" "weighted" infant sleep products, the CPSC would be required to communicate that information to each manufacturer of applicable products, including Nested Bean. 15 U.S.C.

§ 2055(c). Nested Bean has received no such information from the CPSC, which implies that the CPSC does not have information to support its warnings.

158. The CPSC’s failure to provide the required supporting evidence for its claims against “weighted” infant sleep products fails to comport with the requirements of 15 U.S.C. § 2055(b)(6). Issuing inaccurate and misleading public guidance is “not in accordance with” or “in excess of” CPSC’s statutory authority. 5 U.S.C. § 706(2)(C).

159. On information and belief, the CPSC is conflating research about the risks related to soft, loose materials in the sleep environment generally, with the non-defined category of “weighted” sleepwear. The CPSC claims to follow the guidance of the CDC and NIH, which themselves claim to follow the guidance of the AAP. But the AAP’s guidance is based on only one study of “weighted” infant sleep products, and the results of that study do not suggest that “weighted” infant sleepwear poses a danger. The CPSC’s lack of evidence to support its public statements that “weighted” infant sleep products are dangerous renders these statements inaccurate and misleading and, therefore, in violation of 15 U.S.C. § 2055(b)(6).

160. Further, the CPSC failed to define the category of “weighted infant sleep products” before issuing its Safe to Sleep® guidance. The CPSC’s recommendation was based on a hopelessly vague categorization of “weighted” products.

161. Within Directive 1450.2, the program clearance requires that agency statements “accurately reflect[] the status of programs and projects, enforcement activities, litigation and planning[.]”

162. The CPSC issuance of guidance warning against the use of “weighted” infant sleep products does not accurately reflect the status of programs and project, enforcement activities, litigation, or planning.

163. And the editorial clearance provision of Directive 1450.2 requires that statements made by the CPSC or its officials “retain[] style and coherence without changing technical, program, or legal meanings.” The guidance issued by CPSC against weighted infant sleep products fails these threshold requirements that apply “Commission-wide, to all employees, agents and representatives (including contractors), for use when initiating the public disclosure of information (including periodicals, publications and audiovisuals) that reflects on the safety of consumer products. See Directive 1450.2

164. Because of these failures, consumers and retailers incorrectly believe that Nested Bean’s products have caused multiple infant deaths. But Nested Bean’s products—though among the lightest weighted—were arbitrarily identified as part of an undefined “weighted” category based solely on marketing labels and reputation, rather than on verified physical characteristics or safety hazard data.

165. Nested Bean’s identity was readily ascertainable through public CPSC statements as evidenced by (a) Amazon’s sending notices to all prior purchasers of Nested Bean products to alert them that CPSC had issued a safety warning about these “weighted” products, and (b) Target’s near-immediate contacting Nested Bean to discuss the safety of its products.

166. Because Nested Bean’s identity was readily ascertainable, the CPSC was also statutorily required to provide at least fifteen days’ notice to Nested Bean before making the public disclosure. 15. U.S.C. § 2055(b)(1). Issuing public disclosures without providing notice to readily ascertainable manufacturers “not in accordance with” and “in excess of” CPSC’s statutory authority under the CPSA. 5 U.S.C. § 706(2)(C).

167. Therefore, CPSC’s issuance of public guidance warning against the use of “weighted” infant sleep products exceeds its statutory authority and should be held unlawful.

Count Two

Ultra Vires Acts Violation of 15 U.S.C. § 2055(b)(1) and (6)
(Against HHS, NIH, CDC, CPSC)

117-168. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

169. Alternatively, Plaintiff asserts a direct claim against the CPSC for violation of 15 U.S.C. § 2055(b)(1) and (6), assuming that this statute is self-executing. *See Devillier v. Texas* 601 U.S. 285, 291 (2024) (citing *Knick v. Twp. of Scott*, 588 U.S. 180, 192 (2019)).

170. The CPSC's publication of the Safe to Sleep® guidelines advocating against "weighted" infant sleep products violates the requirements of 15 U.S.C. § 2055(b)(1) and (6) because the statements are inaccurate and misleading, and the CPSC failed to provide the required notice to readily ascertainable manufacturers.

171. The CPSC failed to ensure that its disclosures were not inaccurate or misleading; the CPSC relied on unsupported conclusions from the CDC and NIH (which in turn relied upon unsupported conclusions of the AAP), and failed to conduct its own research or verify the accuracy of the claims before making the disclosures.

172. CPSC relied on the AAP's misinterpretation of research that did not actually demonstrate that weighted products are dangerous, and which does not support the guidelines promulgated by the CPSC.

173. CPSC disregarded research provided by Nested Bean directly that demonstrated the safety of Nested Bean's products.

174. Further, CPSC knew from its own Market Scan that some products not marketed as weighted were actually heavier than some products labeled as "weighted." Therefore, it was aware that warning consumers about "weighted" products would (a) cause confusion and (b) erroneously lump in some lighter products while leaving out heavier products.

175. The disclosures were misleading because CPSC failed to define the “weighted” product category, causing confusion for customers and retailers that misidentified Nested Bean’s products as dangerous.

176. Nested Bean’s identity was readily ascertainable through the CPSC’s public disclosures, as evidenced by communications from Target and Amazon, and Nested Bean was not provided with the required notice as a readily ascertainable manufacturer.

177. Therefore, CPSC violated 15 U.S.C. § 2055 in its public disclosures warning against weighted infant sleepwear.

Count Three
Ultra Vires Acts
(Against HHS, NIH, & CDC)

178. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

118.179. Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law” or is “in excess of statutory authority.” Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law” or is “in excess of statutory authority.” authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

119.180. A plaintiff may also “institute a non-statutory review action” against an agency head “for allegedly exceeding his statutory authority.” *Chamber of Com. of U.S. v. Reich*, 74 F.3d 1322, 1327–28 (D.C. Cir. 1996).

120.181. Section 702 of the APA permits a party to bring a non-statutory review action against an agency even if the action challenged is not final. See *Apter v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579, 589–90 (5th Cir. 2023).

121. Ultra vires review is appropriate under the APA, *see Apter v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579, at 587, and, in the alternative, it is appropriate under the common law, *see Fed. Express Corp. v. U.S. Dep’t of Commerce*, 39 F.4th 756, 763 (5th Cir. 2023), and, in the alternative, it is appropriate under the common law, *see Fed. Express Corp. v. U.S. Dep’t of Commerce*, 39 F.4th 756, 763–64 (D.C. Cir. 2022).

183. “[A]n agency literally has no power to act, ..., ... unless and until Congress confers power upon it. An agency may not confer power upon itself.” *Louisiana Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986).

184. “Where a statute’s language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer.” *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 363 (2018).

185. Agency officials’ “power to act and how they are to act are authoritatively prescribed by Congress, so that when they act improperly ... what they do is ultra vires. Because the question [whether framed as an incorrect application of agency authority or an assertion of authority not conferred] is always whether the agency has gone beyond what Congress has permitted it to do” *City of Arlington v. FCC*, 569 U.S. 290, 297–98 (2013).

186. The Public Health Service Act authorizes HHS, and its subagencies NIH and CDC, to “develop, support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood,” such as collecting data, educating the public, and collaborating with federal and state agencies. 42 U.S.C. §§ 300c-11(a), 300c-13.

187. The PHSA requires the Secretary of HHS to make regular reports to Congress describing all the activities being carried out by the HHS, CDC, and NIH; data collection; and

assessment of various approaches related to stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood. 42 U.S.C. §§ 300c-13(b), 300c-14.

188. Nothing in the PHSA authorizes the HHS, NIH, or CDC to opine on the safety or risk of consumer products.

189. The issuance of public statements by an agency advocating for or against a particular action by the public is final agency action subject to judicial review. See Apter, 80 F.4th at 590.

190. The HHS, NIH, and CDC have, as part of their public Safe to Sleep® guidance, advised the public to *not* use weighted infant sleep products.

191. Therefore, the CDC's and NIH's actions opining on the safety or risk of a consumer product and advising the public against the use of weighted infant sleep products were *ultra vires*.

192. This ultra vires challenge is brought under the APA, or alternatively, under the common law.

Count Four
Violation of Administrative Procedure Act Excess of Statutory Authority
(against HHS, CDC, & NIH)

193. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

194. Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law” or is “in excess of statutory ... authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

195. The Public Health Service Act does not authorize the HHS, CDC, or NIH to opine on the safety of consumer products. Therefore, their statements advising against the use of “weighted” products are in excess of their statutory authority.

196. HHS, CDC, and NIH have been granted limited authority to investigate the causes of Sudden Infant Death Syndrome (SIDS). SIDS is the sudden, unexpected death of a baby younger than one year of age that doesn't have a known cause, even after a complete investigation.⁶²

197. NIH previously funded SIDS research focusing on potential causes of SIDS, including brainstem defects and prevention strategies. CDC collects data on SIDS and supports prevention through public outreach. Both agencies participated in the Safe to Sleep® campaign, which engaged in “outreach activities and educational materials to promote safe sleep for babies.”⁶³

198. In April 2025, the Trump administration cancelled federal participation in the Safe to Sleep® SIDS campaign.⁶⁴

199. At no point did the SIDS-related research duties of these agencies permit opining on the safety of purported categories of consumer products, and it certainly is not within their now-narrowed SIDS research participation.

200. The statements published by HHS, CDC, and NIH warning the public against the use of “weighted” infant sleep products exceed their statutory authority.

201. Therefore, the sleep guidance published by CDC and NIH were in excess of statutory authority and should be held unlawful.

⁶² Sudden Infant Death Syndrome (SIDS) and Vaccines, (Dec. 20, 2024), <https://www.cdc.gov/vaccine-safety/about/sids.html>.

⁶³ About SUID and SIDS, (Sep. 17, 2024), <https://www.cdc.gov/sudden-infant-death/about/index.html>.

⁶⁴ Ismael M. Belkoura, NIH cancels participation in Safe to Sleep campaign that decreased infant deaths, Stat10 (Apr. 30, 2025), <https://www.statnews.com/2025/04/30/nih-ends-participation-in-safe-to-sleep-campaign-to-prevent-infant-deaths/>.

Count Five

Violation of Administrative Procedure Act, Arbitrary, Capricious, An Abuse of Discretion, or Otherwise Not in Accordance with Law (against HHS, CDC, & NIH)

202. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

203. Alternatively, if such authority is found to be within the scope of these agencies' responsibilities related to SIDS research, their statements relating to "weighted" infant products were arbitrary, capricious, or an abuse of discretion in violation of the APA.

204. Under the APA, a court must "hold unlawful and set aside agency action" that is arbitrary or capricious, an abuse of discretion, or without observance of procedure required by law. 5 U.S.C. § 706(2)(A).

205. Failing to engage in "reasoned decisionmaking" renders an agency action arbitrary and capricious. *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998) (internal quotation omitted). An "agency action is lawful only if it rests on a consideration of the relevant factors" and "important aspect[s] of the problem." *Michigan v. EPA*, 576 U.S. 743, 750–52 (2015) (internal quotation marks omitted) (requiring "reasoned decisionmaking"). This means agencies must "examine all relevant factors and record evidence." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017).

206. An "agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made[.]" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

207. Agency actions are arbitrary or capricious when, as here, the agency has "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that

runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.*

208. Upon information and belief, the CDC and NIH did not engage in reasoned decision-making when they decided to adopt and publish statements advocating against “weighted” infant sleep products. They relied on the unsupported conclusions of the AAP,⁶⁵ which cited a single study that did *not* recommend against the use of “weighted” infant sleep products. In fact, that study found “weighted” products beneficial.

209. Upon information and belief, the CDC and NIH have conflated research on the risks of soft bedding generally, with research on “weighted” sleep products. There is a significant body of research focusing on the risks of soft bedding in the sleep environment. But existing research on “weighted” products does not suggest a danger. It is arbitrary and capricious to lump “weighted” sleepwear into the category of soft bedding when other sleepwear does not receive this treatment, and the agencies can point to no research that supports their stance.

210. Therefore, the sleep guidance published by CDC and NIH was arbitrary and capricious and should be held unlawful.

Count Six
Ultra Vires Acts
(Against Commissioner Trumka)

211. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

⁶⁵ <https://www.cdc.gov/sudden-infant-death/about/index.html> (“CDC supports the 2022 recommendations issued by the American Academy of Pediatrics (AAP) to reduce sleep-related infant deaths”); <https://safetosleep.nichd.nih.gov/reduce-risk/reduce> (“The actions listed here and in Safe to Sleep® materials and publications are based on the AAP Task Force recommendations.”).

212. Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law” or is “in excess of statutory ... authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

213. A plaintiff may also “institute a non-statutory review action” against an agency head “for allegedly exceeding his statutory authority.” *Reich*, 74 F.3d at 1327–28.

214. Section 702 of the APA permits a party to bring a non-statutory review action against an agency even if the action challenged is not final. *See Apter*, 80 F.4th at 589–90.

215. Ultra vires review is appropriate under the APA, *see Apter*, 80 F.4th at 587, and, in the alternative, it is appropriate under the common law, *see Fed. Express Corp.*, 39 F.4th at 763–64.

122. “[A]n agency literally has no power to act ... unless and until Congress confers power upon it. ... An agency may not confer power upon itself.” *Louisiana Pub. Serv. FCC.*, 476 U.S. 355, 374 (1986).

216. *Comm'n*, 476 U.S. at 374.

123.217. Where a statute’s language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer.” *SAS Inst., Inc. v. Laneu*, 584 U.S. 357, at 363 (2018).^{124.}

218. An agency’s Agency officials’ “power to act and how they are to act are authoritatively prescribed by Congress, so that when they act improperly, what they do is ultra vires. Because the question —[whether framed as an incorrect application of agency authority or an assertion of authority not conferred—] is always whether the agency has gone beyond what Congress has permitted it to do,....” *City of Arlington v. FCC*, 569 U.S. 290, at 297–98 (2013).^{125.}

The PHSA authorizes HHS, and its subagencies NIH and CDC, to “develop,

~~support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood,” such as collecting data, educating the public, and collaborating with federal and state agencies.~~ 42 U.S.C. §§ 300e-11(a), 300e-13.

126. The PHSA requires the Secretary of HHS to make regular reports to Congress describing all the activities being carried out by the HHS, CDC, and NIH, data collection, and assessment of various approaches related to stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood. 42 U.S.C. §§ 300e-13(b), 300e-14.

127. Nothing in the PHSA authorizes the HHS, NIH, or CDC to opine on the safety or risk of a consumer product.

128.1. The issuance of public statements by an agency advocating for or against a particular action by the public are final agency actions subject to judicial review. See *Apter v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579, 590 (5th Cir. 2023).

129.1. The HHS, NIH, and CDC have, as part of their public Safe Sleep Guidance, advised the public to *not* use weighted infant sleep products.

130.1. Therefore, the CDC’s and NIH’s actions opining on the safety or risk of a consumer product and advising the public against the use of weighted infant sleep products were *ultra vires*.

Count Three
Ultra Vires Acts (Against Commissioner Trumka)

131.1. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

132.1. Under the APA, a court must “hold unlawful and set aside agency action” that is “not in accordance with law” or is “in excess of statutory . . . authority[] or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A), (C).

133. A plaintiff may also “institute a non-statutory review action” against an agency head “for allegedly exceeding his statutory authority.” *Chamber of Com. of U.S. v. Reich*, 74 F.3d 1322, 1327-28 (D.C. Cir. 1996).

134. Section 702 of the APA permits a party to bring a non-statutory review action against an agency even if the action challenged is not final. *See Apten v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579, 589-90 (5th Cir. 2023).

135. Ultra vires review is appropriate under the APA, *see Apten v. Dep’t of Health & Hum. Servs.*, 80 F.4th 579, 587 (5th Cir. 2023), and, in the alternative, it is appropriate under the common law, *see Fed. Express Corp. v. U.S. Dep’t of Commerce*, 39 F.4th 756, 763-64 (D.C. Cir. 2022).

136.1. “[A]n agency literally has no power to act, . . . , unless and until Congress confers power upon it. . . . An agency may not confer power upon itself.” *Louisiana Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 374 (1986).

137.1. “Where a statute’s language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer.” *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 363 (2018).

138. An agency’s “power to act and how they are to act are authoritatively prescribed by Congress, so that when they act improperly, . . . , what they do is ultra vires. Because the question—whether framed as an incorrect application of agency authority or an assertion of authority not conferred—is always whether the agency has gone beyond what Congress has permitted it to do,” *City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013).

139.219. The CPSA provides the Commission with the authority to determine whether a consumer product presents an unreasonable risk of injury and if so, then it has the authority to create product safety standards. But a mandatory standard must be may not be

adopted unless the Commission finds it necessary to prevent or reduce an unreasonable risk of injury. 15 U.S.C. § 2056(a). And if the Commission may not adopt a rule banning the product unless the Commission finds both that a consumer product presents an unreasonable risk of injury and that there is no feasible product safety standard that would adequately protect the public from this unreasonable risk then the Commission may create a rule banning the product. 15 U.S.C. § 2057. Both a mandatory standard and a product ban must follow the science and data driven process and procedures prescribed by Congress. *See* 15 U.S.C. § 2058.

140-220. The CPSC did not follow the any rule making process before revising its Safe to Sleep Guidance® guidance to state its determination that “weighted” infant sleep products are unsafe. Instead of undertaking the rigorous data- and evidence-driven process designed by Congress, it simply adopted copied the CDC and NIH’s unsupported determinations.

141-221. Likewise, Commissioner Trumka exceeded, or was without, statutory authority under the CPSA to when he unilaterally: (1) determined determined that a product presents an unreasonable risk of injury; (2) advocate advocated for the ban of a product; and (3) make made public statements, social media posts, and send sent letters to retailers, all of which repeated the same statutorily deficient statements.

142-222. Commissioner Trumka also The provisions of CPSA Section 2055 “apply whenever information is to be disclosed by the Commission, any member of the Commission, or any employee, agent, or representative of the Commission in an official capacity.” 15 U.S.C. § 2055(d)(2). Commissioner Trumka exceeded, or was without, authority to publish inaccurate and misleading statements about Nested Bean’s products, from which the public was readily able to ascertain Nested Bean’s identity, without providing advance notice and opportunity for the company to respond. 15 U.S.C. § 2055(b)(1), (b)(6).

223. Commissioner Trumka's statements on CPSC social media accounts are official actions, not protected speech under the First Amendment, because his conduct, as a CPSC Commissioner, was fairly attributable to the government, and he purported to exercise that authority in his social media posts. *See Lindke v. Freed*, 601 U.S. 187, 198 (2024). Trumka "invoked his official authority" in furtherance of his official responsibilities as a Commissioner of the CPSC; he did not make these statements in his personal capacity. *Id.* at 201–02. Trumka's social media pages are not "ambiguous" as to whether they are official or personal. He held himself out as a Commissioner of the CPSC on his social media accounts, he conducted official business on his social media accounts, and he made these statements on the basis of CPSC's Safe to Sleep® guidance. Trumka exercised power "possessed by virtue of [federal] law and made possible only because the wrongdoer is clothed with the authority of [federal] law" even if he misused that power. *Id.* (citations omitted).

224. Nested Bean's identity was readily ascertainable from Commissioner Trumka's link to the Washington Post article, which named Nested Bean, but Commissioner Trumka did not provide the required fifteen days' notice to Nested Bean, whose identity was readily ascertainable, before issuing his statements. 15 U.S.C. § 2055(b)(1).

225. Even if there is no readily ascertainable manufacturer, the CPSA requires that public disclosures not be inaccurate or misleading, and, to ensure accuracy, the CPSA further requires compliance with specific clearance procedures.

226. On information and belief, Commissioner Trumka did not follow the internal clearance process and directives before issuing his statements. *See Directive 1450.2*. Commissioner Trumka's letters to retailers, on official CPSC letterhead, other statements to retailers, and on official CPSC social media accounts used his official title but did not include a

disclaimer to suggest that his opinions were made in his personal capacity and did not necessarily represent the views of the Commission. Additionally, it seems unlikely that his statements meet the clearance standard for Technical and Scientific statements; Plaintiff can locate no supporting data in Commission files or literature, articulated technical judgment, or report prepared by a Contractor and reviewed by Commission staff. See id. at 7(a)(1). It appears that Commissioner Trumka's statements are based on those of the CDC and NIH, which relied on the AAP, which relied on one study of sixteen infants—a study that did not recommend against “weighted” infant sleep products.

227. The Market Scan performed by CPSC staff was not a safety study but merely a collection of information about the weights of various products on the market, performed to assist ASTM in its voluntary standard drafting process.

228. Therefore, Commissioner Trumka's statements warning against “weighted” infant sleepwear on the CPSC website, on his official CPSC social media accounts, and in his direct CPSC-letterhead communications with retailers were *ultra vires*.

Count Seven
Count Four
15 U.S.C. § 2055 Violation
(Against Commissioner Trumka)

229. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

230. Alternatively, if 15 U.S.C. § 2055(b) provides a direct cause of action, Commissioner Trumka's disclosures violated § 2055(b)(1) and (6) because he did not provide the required notice to readily ascertainable manufacturers and his disclosures were inaccurate and misleading, respectively.

231. Nested Bean's identity was readily ascertainable from Commissioner Trumka's post linking to a Washington Post article, which expressly named Nested Bean, and Commissioner Trumka did not provide the required fifteen days' notice to Nested Bean, whose identity was readily ascertainable, before issuing his statements. 15 U.S.C. § 2055(b)(1).

232. Even if there is no readily ascertainable manufacturer, the CPSA requires that public disclosures not be inaccurate or misleading, and, to ensure accuracy, the CPSA further requires compliance with specific clearance procedures. *See Directive 1450.02.*

233. On information and belief, Commissioner Trumka did not follow the internal clearance process and directives before issuing his statements. *See Directive 1450.2.*

234. Commissioner Trumka's letters to retailers, on official CPSC letterhead, other statements to retailers, and statements on official CPSC social media accounts used his official title but did not include a disclaimer to suggest that his opinions were made in his personal capacity and did not necessarily represent the views of the Commission. Additionally, it seems unlikely that his statements meet the clearance standard for Technical and Scientific statements; Plaintiff can locate no supporting data in Commission files or literature, articulated technical judgment, or report prepared by a Contractor and reviewed by Commission staff. *See id.* at 7(a)(1). It appears that Commissioner Trumka's statements are based on those of the CDC and NIH, which relied on the AAP, which relied on one study of sixteen infants—a study that did *not* recommend against “weighted” infant sleep products. The Market Scan performed by CPSC staff was not a safety study but merely a collection of information about the weights of various products on the market.

235. Commissioner Trumka's statements were doubly inaccurate and misleading because the CPSC has not defined the category of "weighted," leaving the public and retailers to identify the product based on an undefined marketing term.

236. Commissioner Trumka's statements to retailers inaccurately and misleadingly claimed that Nested Bean's products were deadly.

237. Commissioner Trumka's statements also misrepresented to retailers that the CPSC had taken action that warranted stopping sales of weighted infant products.

238. Therefore, Commissioner Trumka's statements violated the requirements of 15 U.S.C. § 2055.

Count Eight
Violation of the Administrative Procedure Act, Arbitrary, and Capricious Agency Action
(Against CPSC)

143-239. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

144-240. Under the APA, a court must "hold unlawful and set aside agency action" that is arbitrary or capricious, an abuse of discretion, or without observance of procedure required by law. 5 U.S.C. § 706(2)(A).

145-241. "An agency may not 'depart from a prior policy *sub silentio* or simply disregard rules still on the books.'" *Louisiana v. DOE*, 90 F.4th 461, 469 (5th Cir. 2024) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). "Rather, the agency must 'display awareness that it is changing position.'" *Id.* That means "changes require careful comparison of the agency's statements ~~at T0 and T1,~~ the initial statement and the revised statement, "to ensure that the agency has recognized the change, reasoned through it without factual or legal error, and balanced all relevant interests affected by the change." *Id.* "An agency

cannot shift its understanding of the law between those two times, deny or downplay the shift, and escape vacatur under the APA.” *Wages & White Lion Invs., L.L.C. v. Food & Drug Admin.*, 90 F.4th 357, 381 (5th Cir. 2024) (en banc).

146-242. That means the Commission was required to “provide a ‘detailed justification’ for its change” here. *Id.* ~~ItBecause it~~ did not, so, its decision is “arbitrary or capricious.” *Id.*

147-243. ~~The Commission’s~~Here, the Commission in November 2023 ~~decision~~ ~~to decided~~ ~~not to~~ initiate rulemaking of mandatory safety standards and ~~its~~in December 2024 ~~decision~~ ~~to decided~~ ~~not to~~ retract the Safe ~~to~~ Sleep ~~Guidelines® guidelines~~ and Commissioner Trumka’s statements. The two decisions are irreconcilable. The November 2023 decision to *not* initiate rulemaking of mandatory safety standards for “weighted” infant sleep products was admittedly due to a lack of data identifying a hazard pattern associated with the products. But the December 2024 decision to *not* retract the Safe ~~to~~ Sleep ~~Guidelines® guidelines~~ and Commissioner Trumka’s statements, which claim “weighted” infant sleep products present an unreasonable risk to consumers, did not provide any data. The CPSC ~~did not acknowledge~~ neither acknowledged the existence of ~~the~~its November 2023 decision ~~or attempt~~nor attempted to demonstrate why it ~~now rejects~~rejected its earlier, well-supported conclusion. This is black-letter arbitrary-and-capricious administrative action.

148.1. Also, failing to engage in “reasoned decisionmaking” renders an agency action arbitrary and capricious. *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998) (~~internal quotation omitted~~). An “agency action is lawful only if it rests on a consideration of the relevant factors” and “important aspect[s] of the problem.” *Michigan v. EPA*, 576 U.S. 743, 750-52 (2015) (~~internal quotation marks omitted~~) (requiring “reasoned decisionmaking”). This means

~~agencies must “examine all relevant factors and record evidence.” *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923 (D.C. Cir. 2017).~~

244. 522 U.S. at 374 (internal quotation omitted). An “agency action is lawful only if it rests on a consideration of the relevant factors” and “important aspect[s] of the problem.” *Michigan v. EPA*, 576 U.S. 743, 750–52 (2015) (internal quotation marks omitted) (requiring “reasoned decisionmaking”). This means agencies must “examine all relevant factors and record evidence.” *Am. Wild Horse Pres. Campaign*, 873 F.3d at 923.

245. “[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made[.]” *Motor Vehicle Mfrs. Ass’n*, 463 U.S. at 43 (quotations and citation omitted).

149-246. Agency actions are arbitrary or capricious when, as here, the agency has “entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.* *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

150-247. Upon information and belief, the CPSC did not engage in reasoned decision-making when it decided to adopt and publish the Safe to Sleep Guidance® guidance advocating against “weighted” infant sleep products.

248. CPSC was aware, as of November 2023, that insufficient data existed for the non-defined “category” of “weighted” infant sleep products (evidenced by its ASTM correspondence), yet it still decided to publish its Safe to Sleep® guidance in, or around, December 2023 recommending against “weighted” infant sleepwear.

249. CPSC blindly followed the unsupported conclusions of the CDC and NIH, which relied on unsupported guidance from the AAP, which cited a lone study (2020 NICU Study) that expressly fails to support the AAP's stance.

250. Plaintiff has been unable to locate any evidence CPSC could have relied upon to meet the requirements of Directive 1450.2 for clearance of technical and scientific statements published on the CPSC website. When there is “not a ‘shred of evidence’ supporting the agency’s decision,” it is arbitrary and capricious. *Calio v. Pa. Dep’t of Transp.*, 101 F. Supp. 2d 325, 331 (E.D. Pa. 2000), *aff’d*, 276 F.3d 576 (3d Cir. 2001) (referencing *Matter of Bell Petroleum Servs., Inc.*, 3 F.3d 889, 905 (5th Cir. 1993)).

151-251. Likewise, the Commission did not provide any reasoned decision-making as for its decision to why it denied Nested Bean’s Retraction Request. The CPSC’s December 19, 2024, decision did not explain why the Commission denied Nested Bean’s request for retraction of both CPSC’s Safe to Sleep Guidance® guidance and Commissioner Trumka’s statements.

152-252. Also, if an agency departs from a prior policy or rule still on the books then it “must ‘display awareness that it is changing position.’” *Louisiana*, 90 F.4th at 469 (quoting *Fox Television Stations*, 556 U.S. at 515).

153-253. The issuance of the Safe to Sleep Guidance® guidance and its refusal to retract the same is a departure from the longstanding rule that requires the Commission to follow the CPSA procedure for determining whether a consumer product presents an unreasonable risk to consumers.

154-254. The December 2024 decision does not acknowledge, much less explain, its change in position.

255. Further, the Commission's removal of some of the statements at issue in this case from its Safe to Sleep® guidance on the CPSC website in August/September 2025 and subsequent reinstatement of the guidance without explanation or further research, just a few days later, suggests these decisions are being made without the required reasoned decisionmaking, rendering the action arbitrary and capricious.

256. If the CPSC had in its possession, at any time, new "information as to any significant risk associated with" "weighted" infant sleep products, the CPSC would be required to communicate that information to each manufacturer of the product, including Nested Bean. 15 U.S.C. § 2055(c). Nested Bean has received no such information from the CPSC, which implies that the CPSC does not have information to support its warnings or change in position.

155-257. Each of these failures renders the Commissions'Commission's actions arbitrary and capricious under the APA.

Count Five
Count Nine
Violation of the Administrative Procedure Act, Failure to Observe Procedure Required by Law (Against CPSC)

156-258. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

157-259. A "reviewing court shall hold unlawful and set aside agency action - found to be without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

158-260. The purpose of the notice-and-comment rulemaking is to give the public the "opportunity to participate in the rule making through submission of written data, views, or arguments" 5 U.S.C. § 553(c).

159-261. A foundational premise of administrative law is to provide due process protections to the public when ~~the~~ unelected agencies make decisions, through adjudication or rulemaking, that have the force and effect of law and affect the public's rights and obligations.

160-262. These requirements "are not mere formalities" but rather "are basic to our system of administrative law." *NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018). ~~That is why When~~ agencies ~~must fail to~~ "subject their substantive rules to notice and comment" ~~otherwise the,~~ ~~those~~ rules "may not be enforced." *W&T Offshore, Inc. v. Bernhardt*, 946 F.3d 227, 237 (5th Cir. 2019).

161-263. The Commission did not follow the CPSA's science- and data-driven process and procedures, nor did the Commission follow the notice and comment requirements for rule-making procedure under the APA and ~~the~~ CPSA when it issued its Safe ~~to~~ Sleep ~~Guidanee® guidance~~ determining that "~~weighted~~" infant sleep products present an unreasonable risk to consumers.

264. On several occasions, Nested Bean has provided the CPSC with detailed safety data and scientific research regarding its products. This included evidence about the minimal weight of its products and their careful, safety-based design. Nonetheless, the CPSC issued the Safe to Sleep® guidance without considering this manufacturer feedback.

265. Despite Nested Bean's proactive engagement and good faith attempts to provide scientific data and evidence, the CPSC proceeded with its unfounded public statements about the dangers of "weighted" products without considering the safety nuances or scientific data provided by Nested Bean. This failure to consider critical feedback violated the CPSA and APA .

Count SixTen
Violation of the Fifth Amendment
(Against Commissioner Trumka)

162-266. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

163-267. “No person shall … be deprived of life, liberty, or property, without due process of law[.]” U.S. Const. Amendamend. V.

164-268. This Court is authorized to set aside laws, rules, regulations, and executive actions that are in violation of the constitutionally guaranteed rights of the citizens of the United States.

165-269. “A fair trial in a fair tribunal is a basic requirement of due process.” *In re Murchison*, 349 U.S. 133, 136 (1955).

166-270. A fair trial in a fair tribunal means the judge has “no actual bias against the defendant.” *Bracy v. Gramley*, 520 U.S. 899, 904–05 (1997).

167-271. As such, “~~recusal~~” “[r]ecusal is required when, objectively speaking, ‘the probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable.’” *Rippo v. Baker*, 580 U.S. 285, 287 (2017) (citation omitted).

168-272. The question is “not whether a judge harbors an actual, subjective bias, but instead whether, as an objective matter, the average judge in his position is likely to be neutral, or whether there is an unconstitutional potential for bias.” *Williams v. Pennsylvania*, 579 U.S. 1, 8 (2016) (quotation and citation omitted).

169-273. The due process requirement of a fair tribunal “applies to administrative agencies which adjudicate as well as to courts.” *Withrow v. Larkin*, 421 U.S. 35, 46 (1975) (citation omitted).

170-274. “[W]hen an administrator unnecessarily makes prejudicial remarks outside an authorized proceeding, the court is more likely to find a violation of due process.” *Zen Magnets, LLC v. CPSC*, 968 F.3d 1156, 1171 (10th Cir. 2020).

171-275. When an administrator made prior statements during~~before~~ the course of an authorized proceeding then, the court is “less likely to consider the prior statements as evidence of pre-judgment or its appearance,” ” thereof. *Id.*

172-276. “But even when statements take place in the course of an authorized proceeding, the statements may reflect pre-judgment or its appearance.” *Id.* at 1171. “It is conceivable that a decisionmaker can form an opinion of a party so extreme that it renders the decisionmaker impermissibly biased.” ” *Id.* (quoting Kristin E. Hickman & Richard J. Pierce, Jr., *Administrative Law Treatise* § 7.7, at 868 (6th ed. 2019)).

173-277. Commissioner Trumka has publicly and repeatedly made inaccurate and misleading statements about “weighted” infant sleep products. Those statements were not made during an authorized proceeding. Given his letter and social media campaign against “weighted” infant sleep products, it is clear that Commissioner Trumka has strong negative opinions on the category of these “weighted” products. As such, Commissioner Commissioner Trumka has actual bias against “weighted” infant sleep products and is incapable of neutral unbiased actions concerning these products in the future.

Count Seven
Count Eleven
Violation of Separation of Powers
(Against CPSC)

174-278. Plaintiff incorporates by reference all the preceding material as though fully set forth herein.

175-279. “The executive Power shall be vested in a President,” who must “take Care that the Laws be faithfully executed.” U.S. Const. art. II, § 1, cl. 1. The President, under the Appointments Clause, has the authority to appoint “Officers of the United States.” U.S. Const. art. II, § 2, cl. 2.

176-280. “[T]he Constitution gives the President ‘the authority to remove those who assist him in carrying out his duties.’” *Seila Law LLC v. CFPB*, 591 U.S. 197, 204 (2020) (citation omitted). Generally, the President has unrestricted removal power. *Id.*

177-281. Challenging the constitutionality of an officer’s removal restriction is not limited to cases involving a contested removal. *Id.* at 212. Supreme Court “precedents have long permitted private parties aggrieved by an official’s exercise of executive power to challenge the official’s authority to wield that power while insulated from removal by the President.” *Id.* (citations omitted).

178-282. ~~There are “only two exceptions to the President’s unrestricted removal power. *Id.* at 204. However, if~~ When, as here, the officer is a principal, as opposed to inferior, and the agency “wields significant executive power,” then statutory removal protections are unconstitutional. See *Id.* at 204.

179-283. The CPSC’s Commissioners are principal officers of the United States and are appointed by the President for a term. See 15 U.S.C. 2053 (a).

180-284. The CPSC wields significant executive power. It can unilaterally conduct administrative hearings, issue rules interpreting its enabling statutes, and can seek to impose significant monetary penalties against regulated parties, 15 U.S.C. §§ 2064(f); 15 U.S.C. § 2051; 15 U.S.C. § 2069.

181-285. However According to the CPSA, however, the President may only remove a Commissioner only for “neglect of duty or malfeasance in office but for no other cause.” 15 U.S.C. 2053(a).

182-286. Therefore, the This for-cause removal protections under the CPSA are protection is unconstitutional and violateviolates the separation of powers.

PRAYER FOR RELIEF

Plaintiffs respectfully request that this Court:

A. —— Declare that CPSC’s product safety determination of “weighted” infant sleep products in its Safe to SleepGuidance® guidance violated the CPSA disclosure requirements; is contrary to law, not authorized by law, and in excess of statutory authority under the APA;

B. —— Declare that CPSC’s product safety determination of weighted infant sleep products in its Safe Sleep Guidance is arbitrary and capricious and unlawful under the APA;

C.A. Declare that CPSC’s product safety determination of weighted infant sleep products in its Safe Sleep Guidance and violates the APA because it failed to follow procedure and was promulgated without notice and comment;

D.B. —— Declare that CPSC’s refusal to retract its product safety determination of “weighted” infant sleep products in its Safe to SleepGuidance® guidance and Commissioner Trumka’s public letters and statements regarding the same violated the CPSA disclosure requirements; is contrary to law, not authorized by law, and in excess of statutory authority under the APA; is arbitrary and capricious and unlawful under the APA; and violates the APA because it failed to follow procedure;

E.C. —— Declare that HHS, CDC, and NIH’s product safety determinationdeterminations of “weighted” infant sleep products in itstheir Safe to SleepGuidance is® guidances are ultra vires; are contrary to law, not authorized by law, and in excess of statutory authority under the

APA; and are arbitrary and capricious and unlawful under the APA;

F.D. Declare that Commissioner Trumka's unilateral product safety determination of "weighted" infant sleep products in his public letters and statements is *ultra vires* and violated CPSA disclosure requirements;

G.E. Declare that Commissioner Trumka is impermissibly biased against "weighted" infant sleep products, including Nested Bean's products, in violation of the Fifth Amendment;

H.F. Declare that the Commissioner's Commissioners' for-cause removal protections violate the separation of powers;

I.G. Order Defendants to issue a retraction pursuant to 15 U.S.C.A. Section§ 2055(b)(7) to correct and clarify Commissioner Trumka's inaccurate and misleading public statements regarding "weighted" infant sleep products;

J.H. Enjoin Defendants from making further public disclosures in violation of Section (6)(b) and determining the safety of "weighted" infant sleep products without adherence to the CPSA requirements;

K.I. Enjoin Defendant Commissioner Trumka, preliminarily and permanently, from participating in any future CPSC actions pertaining to "weighted" infant sleep products, including Nested Bean's products;

L.J. An award of Plaintiffs' reasonable attorneys' fees and costs under 42 U.S.C. § 1988; and

M.K. Any further relief this Court deems just and proper.

Respectfully submitted this 28th20th day of MarchOctober 2025.

Respectfully Submittedsubmitted,

/s/ William E. Green, Jr.
William E. Green, Jr. (Bar No.
4864)

M. Jane Brady (Bar No. 1)
~~William E. Green, Jr. (Bar No. 4864)~~ Halloran
Farkas + Kittila LLP
5722 Kennett Pike
Wilmington, DE Delaware 19807
Phone: (302) 467-2954268-6875

mjb@hfk.law

Fax: (302) 257-2019
Email: wg@hfk.law

/s/ Loren A. Seehase
Loren A. Seehase*
Hawaii Bar No. 10414
Pacific Legal Foundation
4440 PGA Blvd., Suite 307
Palm Beach Gardens, Florida 33410
Phone: (916) 530-9060
Fax: (916) 419-7747
Email: LSeehase@pacificlegal.org

/s/ Bridget Conlan
Bridget Conlan*
Illinois Bar No. 6348769
Pacific Legal Foundation
3100 Clarendon Blvd., Suite 1000
Arlington, Virginia 22201
Phone: (202) 888-6881
Fax: (916) 419-7747
Email: BConlan@pacificlegal.org

Counsel for Plaintiff Nested Bean, Inc.
*Admitted pro hac vice